

Chapter 25-B

Participant Follow-Up (Phase II)

U.S. FIELD CENTER ADMINISTRATION

It is recommended that this form 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 it to them by mail for completion. 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 an "N" in the data field for "Date Form Filled Out" on Panel 16-II, Follow-up Questionnaire (Phase II), and the 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 it should not be triggered by the DES.

Phase II annual follow-up will commence on June 1, 2009 for all participants due for annual follow-up and will be conducted for at least three years. 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.

All Proband Generation Participants (including Proband Generation Spouse Controls) will be administered the "expanded" follow-up every year. This includes:

- (a) Annual Follow-up Telephone Contact Questionnaire (Panel 16-II)
- (b) Medical History (Panel 5-II)
- (c) Medication Inventory (Panel 6-II)
- (d) Telephone Interview for Cognitive Status (TICS) (Panel 7b-II)
- (e) NEO Five-Factor Inventory (Panel 11b-II)

Further, the Dementia Questionnaire will be administered to the designated family reporter/proxy (not the participant) following the completion of the telephone interview with the enrolled individual or their designated family reporter/proxy for these Proband generation participants and Spouse Controls. If the interview has already been conducted with the DFR/proxy you can ask the Dementia Questionnaire on the same telephone contact.

All Offspring Generation Participants (including Offspring generation Spouse Controls) will receive the above "expanded" follow-up every third year (i.e., 3rd annual follow-up and 6th annual follow-up). The Dementia Questionnaire is also administered to their Designated Family Reporter/Proxy (not the participant), but only to those Offspring Generation participants and Spouse Controls who are age 60 and older at the time of the annual follow-up telephone call.

For all other years (i.e., 1st, 2nd, 4th and 5th annual follow-up) these participants should only be administered the Annual Follow-Up Telephone Contact Questionnaire (Panel 16-II), as discussed in Chapter 25 of this MOP.

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 clinic, get a letter from family, or from local obituary, etc.) the person is marked as deceased in the DES in the Follow-up module. Once the Follow-up form is marked and entered in the DES, the field center will then initiate the completion of a **Decedent Proxy Interview Form (Panel 18-II)**. All deaths reported from June 1, 2009 and forward during Phase II follow-up are to have this form completed. Details regarding the Decedent Proxy Interview Form are at the end of this Chapter.

DENMARK FIELD CENTER ADMINISTRATION

Expanded 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

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 reintroduce 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).

If you are asked by the participant how many other family members are participating in this study, you can answer provide a global answer (i.e., approximately 15 or whatever is accurate) but you are not permitted to provide names of those participating as it would be a HIPAA violation.

ANNUAL FOLLOW-UP TELEPHONE CONTACT QUESTIONNAIRE (PANEL 16-II)

Mark the header to indicate whether this form was administered to the participant via the telephone, by a designated family reporter/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 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. If deceased, go to Q1b. If the participant is living, continue to Question 2 with the participant or their DFR/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 mark in the DES the status change to deceased for this individual.

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 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 proxy the date of the hospitalization and the reason. If there are more than three hospitalizations, please list them on a separate sheet. If the exact date of the hospitalization is unknown ask for their best estimate; if the date is unknown, indicate as such with a "D". Proceed to Q4a.

Note: Do not record the Code at the time of interview. The hospitalization codes need to be assigned after the phone follow-up. Refer to the table at the end of this section.

Questions 4a-10b: These questions ask about the participant's current functional status. Please note the skip patterns on this form. Refer to Chapter 11 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.

Note: *Questions 11 and 12 will not be completed by the University of Southern Denmark field center as this information is available in their public registers.*

Question 11a: Indicate whether the contact information on file is accurate, has changed or if a move is planned. If there is a change, complete Q11b; otherwise, proceed to Q12a.

Question 11b: Provide updated contact information here. If the participant or their proxy indicate a move, please remind them to call the Field Center (and provide the toll-free telephone number) to update us when they have the new information. Proceed to Q12a.

Question 12a: Confirm the contact person for the participant. If there are any changes, denote them on the form and go to Q12b.

Question 12b: Indicate if the contact person is enrolled in LLFS and go to Q12c.

Question 12c: Verify or change the address, phone, best time to call and email address of the contact person and go to Q12d.

Question 12d: Please check the appropriate relationship between the contact person and the participant (i.e., spouse, daughter, son, niece, nephew, etc.) and go to Q12e.

Question 12e: Please ask whether this individual has power of attorney and check the appropriate response. Proceed to Q13.

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 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.

Note: If this is a 1st, 2nd, 4th or 5th annual follow-up telephone call for an Offspring Generation family member or Spouse Control, then this ends the call. Proceed to End Interview Script below.

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."*

If this is an annual follow-up call to a Proband Generation family member or Spouse Control or the 3rd or 6th follow-up for an Offspring Generation family member or Spouse Control, then proceed to the next panel.

HOSPITALIZATION CODING

a. Heart Disease	
Myocardial Infarction or Heart Attack	A1
Coronary Angioplasty or Coronary Artery Bypass Grafting (CABG)	A2
Heart Failure or Congestive Heart Failure	A3
Atrial Fibrillation/Pacemaker	A4
Deep Vein Thrombosis (or blood clots in legs) or Pulmonary Embolism (blood clot in lung)	A5
Rheumatic Fever or Heart Valve Problems	A6
High Blood Pressure	A7
Other	A8
b. Stroke	
Stroke or Cerebrovascular Accident	B1
Transient Ischemic Attack (TIA) or Mini-Stroke	B2
Other	B3

c. Lung Disease	
Asthma	C1
Chronic Bronchitis	C2
Emphysema or Chronic Obstructive Pulmonary Disease (COPD)	C3
Pneumonia	C4
Pulmonary Fibrosis	C5
Chest Surgery	C6
Other	C7
d. Arthritis	
Arthritis of the Knees, Hips or Spine	D1
Other	D2
e. Endocrine/GI/Kidney	
Diabetes	E1
Thyroid Disease	E2
Osteoporosis	E3
Chronic Liver Disease, Cirrhosis, or Hepatitis	E4
Kidney (Renal) Disease or Failure	E5
Other	E6
f. Neurological	
Alzheimer's Disease or Dementia	F1
Parkinson's Disease	F2
Depression or Anxiety	F3
Other	F4
g. Cancer	
Breast Cancer	G1
Blood Cancer, Leukemia, or Lymphoma	G2
Colon (Bowel) or Rectal Cancer	G3
Lung Cancer	G4
Malignant Melanoma	G5
Other Skin Cancer	G6
Esophageal Cancer	G7
Pancreatic Cancer	G8
Other Cancer	G9
Prostate Cancer	G10
Enlarged Prostate, not cancer	G11

j. Fractures	
Hip	J1
Wrist or Forearm	J2
Spine	J3
Other	J4
k. Other Illnesses not listed above	K1

MEDICAL HISTORY QUESTIONNAIRE (PANEL 5-II)

Mark the header to indicate whether this form was administered to the participant via the telephone, by a designated family reporter/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 time frame. For the first administration of this form at Phase II Follow-up for Proband generation individuals the "since we inquired about this condition" would be the date of their LLFS enrollment in-person or telephone visit. For all subsequent Phase II annual telephone follow-up calls, the date will be the last time this expanded follow-up questionnaire was administered to them. For Offspring generation individuals, there "since we inquired about this condition" date will either be their enrollment in-person or telephone visit or their 3rd annual phone follow-up (which is the expanded telephone contact).

- 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.
- 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 item on the list.
- 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 legion", 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".

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-II)

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

Please ask the participant to gather all prescription and non-prescription medications in their original containers with medication label. If the participant does not have his/her medications available, ask them if you can call them back to obtain this important information. Medications include: pills, tablets, drops, salves, injections, creams/ointments, inhalers, suppositories and dermal patches. Non-prescription medications include: vitamins, aspirin, laxatives, dietary supplements, and herbal preparations.

Using the supplied script, ask the participant whether s/he has taken any prescription or non-prescription medications in the *past 2 weeks*. If the participant replies that no medications are taken and you are certain that the participant has understood the question, check NO and move on to the next assessment form. If the answer is "don't know" or "refused" proceed to the next assessment panel.

Otherwise, write in the complete name, strength and unit(s) of each product onto the Medication Inventory Form. For tablets and capsules, which are the most common formulations, units are usually provided in mg (milligrams). Use the formulation codes provided on the form to indicate whether the medication is taken orally, topically or via some other route. An additional line has been provided to document any notes regarding each medication.

Write the name of each medication on a separate line. Do not record medications that have not been taken during the past two weeks. Record the names of all medications.

After the prescription medications have been transcribed, continue on the next line to list the non-prescription (i.e. over-the-counter) medications and supplements that were taken in the *past 2 weeks*. Record the manufacturer's name of all vitamins and herbal preparations. The strength of herbal preparations and multi-vitamins should be coded as not applicable (N). Attach additional pages as needed.

TELEPHONE INTERVIEW FOR COGNITIVE STATUS (PANEL 7B-II)

For the LLFS Follow-up, the following script should be used to introduce the test. Do not use the suggested script from the Guidelines document.

Interviewer: *"I am going to ask you some questions to test your memory. Some of these are likely to be easy for you, but some may be difficult. Please bear with me and try to answer all the questions as best you can. If you can't answer a question, don't worry. Just try your best. Please do not use any paper, pencils, or calendars to assist you in answering the following questions. Also, be sure that the room is quiet; there should be no television, radio, or music playing. Are you ready?"*

The following three (3) pages provide the general guidelines for administration and scoring for each item, except Item 12. The detailed instructions for Item 12 can be found at the end of this section.

General Guidelines: Although the TICS is simple to administer and score, examiners should be well practiced. Ideally, they should be native English speakers; any variance in pronunciation due to foreign accents should be minimal. Examiners should speak clearly and articulate distinctly.

Before administering the interview, it is essential that the examiner speak with someone other than the person being interviewed (the "examinee"). This may be the examinee's caregiver or a family member who is at the same location and who is able to comprehend and follow basic instructions. This person (the "proctor") must make sure that the environment is appropriate for testing. The examiner should ascertain the examinee's ability to hear spoken language at a conversational volume, as well as the street address where he or she is located. The room where the examinee will be interviewed should be quiet and free from distractions. Ideally, no one other than the proctor should be present. In administering the TICS, the following guidelines should also be taken into consideration:

1. In general, the examinee's answers should precisely match the given scoring criteria. If a precise answer is not given, the examiner should probe for the correct response. For example, if the examinee's response to "What animal does wool come from?" (Item 7) is "a ram" or "ewe" the examiner should say, "Is there another name for that?"
2. Reasonable judgment should be exercised regarding allowing the examinee sufficient time to answer a question before proceeding on to the next question.
3. If an examinee changes an incorrect response to a correct response at any time during the TICS administration session, credit should be given for the new correct response.
4. If an examinee changes a correct response to an incorrect response at any time during the TICS administration session, the new response should be recorded and credit should not be given.

Administration and Item Scoring: Prior to the TICS administration, examiners should ensure that they have a TICS Record Form available. All examinee responses should be recorded *verbatim* in the spaces provided on the Record Form.

Instructions to the Proctor: When the examiner has the proctor on the telephone, the following instructions should be given:

Interviewer Script: *"In a couple of minutes, I am going to be asking [examinee's name] a number of different questions to test [his/her] thinking and memory. Before we start, I need to ask you whether the address I have for your current location is correct. Please don't repeat it out loud if [examinee's name] is in the room with you, since I will be asking [him/her] the same question in a few minutes. Is your current address [examinee's address]?"* If the answer is "no", ask the proctor either to step into another room before giving you the correct address or to have the examinee leave the room briefly before giving you the address. Then go on to say, *"Please be sure that all papers, pencils, books, calendars, newspapers, and everything else that might provide distraction or visual cues are removed from [examinee's name] sight. Also, please be sure that the room is quiet; there should be no television, radio, or music playing."*

"Some of the questions may be difficult for [examinee's name] to answer. [He/She] may ask you for help. If [he/she] does, just encourage [him/her] to do as well as [he/she] can. [He/She] should guess if necessary. Please do not give [him/her] any answers or hints, okay? If you and [examinee's name] are ready, please put [him/her] on the phone."

Instructions to the Examinee: When the examiner has the examinee on the telephone, the following instructions should be given:

Interviewer Script: *"I am going to ask you some questions to test your memory. Some of these are likely to be easy for you, but some may be difficult. Please bear with me and try to answer all the questions as best you can. If you can't answer a question, don't worry. Just try your best. Are you ready?"* These instructions may be repeated verbatim or paraphrased, if necessary. For each of the actual TICS items, except for Item 5 and Item 8, single repetitions are permitted. When the examinee is ready, begin administering the TICS items according to the following instructions.

Item 1: Orientation to Name. Say to the examinee, *"Please tell me your full name."* Score one (1) point for the correct first name (or nickname) and one (1) point for the correct last name. The maximum score is two (2) points.

Item 2: Orientation to Time. Ask the examinee, *"What is today's date?"* Score one (1) point each for correct month, date, year, day of the week, and season. Probe for any of these that are not provided spontaneously (e.g., *"What day of the week is it?"* or *"What season is it?"*). Precisely correct answers are required (e.g. a hot day in early June is not summer). The maximum score is five (5) points.

Item 3: Orientation to Place. Ask the examinee, *"Where are you right now?"* Score one (1) point each for correct house number, street, city, state and zip code. If any of these are not given spontaneously, probe (e.g. *"What number is that?"* or *"What is your zip code?"* – 5-digit zip code is sufficient.) If the examinee is in a facility with no house number (e.g. a hospital or nursing home), the name of the facility may be substituted for the house number. The maximum score is five (5) points.

Item 4: Counting Backward from 20 to 1. Say to the examinee, *"Please count backward from 20 to 1."* If the examinee makes an error on Trial 1, ask him or her to try again. Score two (2) points if completely correct on first trial or one (1) point if correct on second trial. Score zero (0) points if there are any errors on the second trial. The maximum score is two (2) points.

Item 5: Remembering a Word List. Say to the examinee, *"I am going to read you a list of ten (10) words. Please listen carefully and try to remember them. When I am done, tell me as many of the words as you can, in any order. Ready? The words are (Pause): cabin, pipe, elephant, chest, silk, theater, watch, whip, pillow, giant. (Pause). Now tell me all the words you can remember."* The words should be read at approximately one word every two (2) seconds. No repetitions of the word list are permitted by the examiner. Score one (1) point for each correctly recalled word. Score zero (0) points for incorrect responses (e.g. repetitions of list words, intrusions of words not on the list). The maximum score is ten (10) points.

Item 6: Serial 7 Subtractions. Say to the examinee, *"I would like you to take the number 100 and subtract 7."* (Pause for a response.) *"Now keep subtracting 7 from the answer until I tell you to stop."* No further prompts or instructions are given, except to *"keep going"*. Stop the examinee after five serial subtractions. Score one (1) point for each correct subtraction. Do not inform the examinee of incorrect responses, but allow subtractions to be made from the last response. That is, score one (1) point for a correct subtraction, even if the subtraction was from a previously incorrect response. For example, "93, 85, 78, 71, 65" would be awarded three (3) points. The maximum score is five (5) points.

Item 7: Naming to Verbal Description. Ask the examinee:

- *"What do people usually use to cut paper?"* (Pause for a response.) Score one (1) point for *"scissors"* or *"shears"*.
- *"How many things are in a dozen?"* (Pause for a response.) Score one (1) point for *"12"*.
- *"What do you call the prickly green plant that lives in the desert?"* (Pause for a response.) Score one (1) point for *"cactus"*.
- *"What animal does wool come from?"* (Pause for a response.) Score one (1) point for *"lamb"*.

The maximum score is four (4) points.

Item 8: Repetition. Say to the examinee, *"Please repeat this after me: 'No ifs, ands, or buts.'"* (Pause for a response.) Now, please repeat this after me: *"Methodist Episcopal."* No repetitions of the phrases by the examiner are permitted. Score one (1) point for each correct repetition. The maximum score is two (2) points.

Item 9: Recent Memory. Ask the examinee, *"Who is the President of the United States right now?"* (Pause for a response.) *"Who is the Vice-President?"* Score one (1) point for current president's full (i.e., first and last) name. Score one (1) point for current vice-president's full (i.e., first and last) name. If only the last name is given, probe for the full name. The examinee must provide both first and last name in order to receive credit for each question. The maximum score is two (2) points.

Note: If the TICS is used in another English-speaking country (e.g., Canada, United Kingdom) the examiner should modify this question using the correct titles for the head of state.

Item 10: Praxis. Say to the examinee, "*With your finger, tap five times on the part of the phone you speak into.*" If the TICS is being administered in person (e.g., to a visually impaired person), the examinee should be asked to tap on the table rather than on a telephone receiver. Score two (2) points if five taps are clearly heard, one (1) point if either more than or fewer than five (5) taps are heard, and zero (0) points if no taps are heard. The maximum score is two (2) points.

Item 11. Opposites. Say to the examinee, "*I am going to say a word and I want you to give me its opposite. For example, if I said 'hot', you would say 'cold'.*"

- "*What is the opposite of west?*" (Pause for a response.) Score one (1) point for "*east*".
- "*What is the opposite of generous?*" (Score one (1) point for "*cheap*", "*stingy*", "*tight*", "*selfish*", "*greedy*", "*mean*", "*meager*", or other correct antonym.

The maximum score is two (2) points.

Item 12: "*Earlier I read you a long list of words that I asked you to remember. I would like you to try to tell me as many of the words as you can remember now.*" Maximum score is 10 points.

Calculating the TICS Total Score: To obtain the TICS Total score, sum the number of points obtained for each of the eleven (11) items. A maximum of 41 points may be obtained. The examiner should exercise care to ensure that the appropriate number of points is awarded for each answer and that the addition is done correctly. The TICS Total score should be entered in the space provided on the first page of the TICS Record Form.

Item 13-14: Scoring note: We have two (2) scores, maximum of 41 when Item 12 is excluded **Q13**, and a maximum of 51 when Item 12 is included, **Q14**.

Items 15a-15d: Interviewer needs to answer **Q15a** regarding the overall validity of the TICS test. If the Interviewer deems the test invalid, please answer **Q15b-Q15d** regarding the reasons for the test to be considered invalid.

At the conclusion of the TICS, thank the examinee for his or her participation and terminate the telephone call.

NEO FIVE-FACTOR INVENTORY (PANEL 11B-II)

The complete five-factor inventory (60 questions) will be administered for the expanded telephone follow-up. We have added the domains of Extraversion, Agreeableness, and Openness to Experience to those of Conscientiousness and Neuroticism which were collected during the enrollment in-person or telephone examination. If the participant is hard of hearing and cannot complete this form via telephone, it can be mailed. If the form is mailed, please be cognizant of the study data collection windows so that every effort is for this form to be completed and returned to

the field center within the data collection window. If that is not possible, it is better to have complete data returned late, than no data at all.

Methods: This questionnaire should be administered to the participant or their designated family reporter/proxy. When this form is administered to the study participant, the following script is used:

Interviewer Script: *"Now I'm going to read some statements. Listen carefully. For each statement, choose the response on this card that best represents your opinion. Choose strongly disagree (1) if the statement is definitely false for you, choose Disagree (2) if the statement is mostly false, choose Neutral (3) if you can't decide, choose Agree (4) if the statement is mostly true, and choose Strongly agree (5) if the statement is mostly true for you. For example, if statement was "I laugh easily", and this was definitely true for you, you would say "strongly agree" (or choose Category 5).*

Important Scoring Note: If the respondent answers "I don't know", this is marked as "neutral". When this questionnaire is administered to a designated family reporter/proxy it may be sometimes difficult to administer this questionnaire to them. In such instances, please make every effort to put them at ease and that they are being asked these questions based on their knowledge of this person, their characteristics, etc. They should not be worried about their answers, there is no right or wrong answers, we are just asking for their perception of the person.

The following script should be used to introduce the questionnaire to DFR/proxy's:

Interviewer Script: *"Now I'm going to read some statements. Listen Carefully. For each statement, choose the response that best represents your opinion regarding [insert Name Here]. For each statement, choose the response on this card that best represents your opinion. Choose strongly disagree (1) if the statement is definitely false for you, choose Disagree (2) if the statement is mostly false, choose Neutral (3) if you can't decide, choose Agree (4) if the statement is mostly true, and choose Strongly agree (5) if the statement is mostly true for you. For example, if statement was "I laugh easily", and this was definitely true for you, you would say "strongly agree" (or choose Category 5)."*

Important Scoring Note: If you receive 10 "I don't know" (i.e., neutral) responses in a row, you can stop administering the questionnaire. The remainder of the questions should be marked as "R" in the DES.

Alternate Phrasing of Unfamiliar Words: If the participant is not familiar with a word used in a statement, you may give them a synonym for the unfamiliar word. These substitutions should only be used if the participant says they do not understand the word or phrase. Suggested substitutions are listed question-by-question below.

Bolded text is modification to original item:

1. None needed
2. None needed
3. I don't like to waste **or spend too much time** daydreaming, **or thinking or dreaming about things during the day.**
4. I try to be courteous **or polite** to everyone I meet.
5. I try to keep my belongings **and things** clean and neat.
6. I often feel inferior **or not as good as / less important than** others.

7. None needed
8. None needed
9. I often get into arguments with my family and [coworkers] **classmates**.
10. I'm pretty good about pacing myself **or giving myself enough time (taking the right amount of time)** so as to get things done on time.
11. When I am under a great deal of stress, sometimes I fell like I'm going to pieces **or I'm going to fall apart**.
12. I don't consider myself especially "light hearted" **or easy going, relaxed**.
13. I am interested by the patterns I find in art and nature; **I am interested in art and nature**.
14. Some people feel that I am selfish and egotistical; **that I only care about myself or spend a lot of time thinking about myself**.
15. I am not a very methodical **or planful, orderly person**.
16. I rarely (**hardly ever**) feel lonely or blue.
17. None needed
18. I believe letting children hear controversial speakers **with whom many people disagree** can only confuse and mislead them.
19. I would rather cooperate **or work together** with others than compete with them.
20. I try to perform all the tasks assigned to me conscientiously **or carefully; mindfully**.
21. I often fell tense or jittery; **nervous, shaky**.
22. None needed
23. Poetry has little or no effect on me; **poetry doesn't do much for me**.
24. I tend to be cynical and skeptical of others' intentions; **I think other people have bad intentions, I don't trust people**.
25. I have a clear set of goals **or things I want to do**, and I work toward them in an orderly fashion (**a certain order**).
26. Sometimes I feel completely worthless **or of no use or value**.
27. None needed
28. None needed
29. I believe that most people will take advantage of you, **or use you for their benefit**, if you let them.
30. I waste a lot of time (**spend too much time**) before settling down to work.
31. I rarely (**hardly ever**) feel fearful or anxious **or afraid**.
32. None needed
33. I seldom (**don't often**) notice the moods or feelings that different environments produce; **in other words, I don't often notice the moods or feelings different places have or notice feeling different in different places**.
34. None needed
35. I work hard to accomplish my goals; **to finish the things I want to do**.
36. None needed
37. I am a cheerful, high spirited **or happy** person.
38. I believe we should look to our religious authorities (**leaders**) for decisions on moral issues **or to help us with problems about what is right and wrong**.
39. Some people think of me as cold and calculating **or unemotional and sneaky**.
40. When I make a commitment, I can always be counted on to follow through; **When I say I'll do something, I do it**.
41. None needed
42. I am not a cheerful optimist; **I am not a happy person who is hopeful about the future**.
43. Sometimes when I am reading poetry or looking at a work of art, I feel a chill or a wave of excitement; **I get excited**.

44. I'm hard-headed and tough-minded **or stubborn** in my attitudes; **in other words, I don't change my mind easily.**
45. Sometimes I am not as dependable or reliable (**or trustworthy**) as I should be.
46. I am seldom (**not often**) sad or depressed.
47. My life is fast-paced **or busy; in my life, a lot happens all the time.**
48. I have little interest in speculating on the nature of the universe or human condition; **in other words, I am not really interested in trying to figure out the meaning of things or people.**
49. I generally try to be thoughtful and considerate **and kind.**
50. I am a productive **or hard working** person who always gets the job done.
51. I often feel helpless (**powerless**) and want someone else to solve my problems.
52. None needed
53. I have a lot of intellectual curiosity; **I am curious about learning.**
54. None needed
55. I never seem to be able to get organized; **to get my things in an orderly, neat way.**
56. At times I have been so ashamed **or feel so bad about myself that** I just want to hide.
57. None needed
58. I often enjoy playing with theories and abstract ideas; **I often enjoy playing with ideas and guesses about the meaning of things and I enjoy trying to figure out things.**
59. If necessary, I am willing to manipulate, **trick or use people** to get what I want.
60. None needed

Alternative phrasings adapted from Markey PM, Markey CN, Tinsley BJ, Ericksen AJ. A preliminary validation of preadolescents' self-reports using the Five-Factor Model of personality JOURNAL OF RESEARCH IN PERSONALITY 36 (2): 173-181 APR 2002.

DEMENTIA QUESTIONNAIRE (DQ)

The Dementia Questionnaire for LLFS is based on the original DQ developed by Kawas et al. 1994 with modifications from the Cardiovascular Health Study and WHICAP.

The DQ is a brief interview that assesses cognitive and functional status of the participant in the following domains: memory and cognition, expression (language), daily functioning, recognition of problems (insight), and other medical and psychiatric difficulties. While most DQ questions are answered in a multiple-choice format, marginal notes are required to assist in the interpretation of responses.

General Rules for Administration: Ask for specific examples of the ability or inability to perform a given activity, and include enough probes to help the informant determine the reason for the problem. Specific probes are provided on the form for this purpose. These probes should be followed up by restating the response (e.g., "*So you said that you always accompany your mother out of the apartment because she got lost a few times last month – would you say this interferes with their daily living?*")

With each of the items in the first section the informant may report that the participant has always had difficulty. To probe for this ask, "*Do you think you/they could do it better a year ago?*"

If the informant reports that they never did or do not want to do the activity, ask "*Do you think they could do it if they had to?*" Handling money is an item to which informants often respond that the participant does not do it. In such cases ask about the informant's view of whether they have the ability to do it: "*Do you think /he/she could make change for purchases if/he/she had to?*"

Before presenting Item 1 say: *"You have been identified by [participant's name] as someone who would be able to answer questions about his/her health and well-being. I would like to ask you some questions about [participant's name] memory and other health related items that may interfere with his/her daily living. The reason we are asking these questions is so we can get another perspective on [participant's name] health and well-being."* If this is a repeat follow-up, then add that we are interested in your perspective on [participant's name] changes since we last interviewed you on [insert date of last interview].

- Item 1: Memory Problem.
 - Ask: ***"Does participant's name have any problems with his/her memory?"*** Mark the informant's answer, Yes or No. If the informant reports Yes, go on to ask about date of onset and the other details.
 - Ask: ***"Around what time would you say this started?"*** Record the date in the space provided - Month and Year.
 - Informants rarely have an exact date that they can provide for this answer. However you must use your interviewing skills to help them. Using events or holidays as benchmarks may help the informant. However if the problems began after a stroke or some other event or accident, the exact date may be able to be produced. If they come up with a month, Ask them beginning/middle/end? If they come up with the year, help to narrow it down to the month or season. You may have to write in the margins to help record what is reported.
 - If an exact date is not possible to pin down, but you are able to get month and year, record the 15th of the month.
 - If the informant is able to narrow it down to a year, record June 15th of that year.
 - If the informant is able to narrow it down to a couple of years, choose the midpoint.
 - State: ***"You said that their memory has not been the same since [date of onset]. Can you describe what kinds of problems they have been having with their memory?"*** Attempt to obtain as many details and descriptions as possible about the nature of the memory problems, and the effect they have had on the participant's life.
 - Ask: ***"Who first noticed their memory problem(s)?"*** Record the relationship of the person to the participant and the circumstances surrounding this first notice of problems.
- Continue with Items 2-7, asking: ***"Does (participant's name) have any problems with _____ that interferes with daily living?"*** Mark the informant's answer, Yes or No.
 - Ask for an example for each item to which they respond "Yes".
 - If the informant reports "Yes", proceed with inquiring about the date of onset or age of onset and other details and examples.
- Item 8. Ask: ***"Would you say that these problems started all of a sudden or gradually(slowly)?"*** Circle the informant's answer and describe any details about the course of the problems that are provided.
- Item 9: Ask: ***"Would you say that there has been a steady decline in his/her memory since [date of onset]? Or has [his/her] memory been worse since [date of onset] and remained stable, or at the same level? Has there been further decline in memory since [date of onset] that is not gradual, but stepwise, like drops all of a sudden, then stable, then another drop..."*** Each of these questions try to probe into the course of the decline. Record the description that the informant agrees with and any details they provide you about the course of their memory problems.
 - Examples on how to answer number 9:
 - Ask: ***"Would you say that the memory problems have been continuous or that there are some days when his/her memory is better than others?"*** Record the informant's characterization of whether there is fluctuation in their memory.
 - Ask: ***"Did the memory problems begin around the same time as a medical, emotional or physical event in his/her life, like the death of a loved one, an accident, or an illness?"*** Record the informant's view of whether the onset of the memory problems coincided with an

event.

- Ask: "***Did your memory problems start before or after his/her _____ problems began?***" Record any details provided about the timing of the memory problems with a cerebrovascular event or onset of EPS.
- The informant should be read as much information as is needed from the anchor descriptions in order to answer the question as accurately as they can. Make sure it is clear that they need to think about the statements in terms of [participant's name] ability to live on their own (independence).
- Items 10-12 Verbal Expression. Ask examples for each and date or age of onset.
- Items 13-20 Daily Functioning. Ask the items as described and score not only those behaviors that are due to physical limitations but also to cognitive problems. For example a participant with Parkinson's Disease or severe arthritis may have difficulty with buttons and require complete assistance getting dressed. However, for someone who performs any aspects of their own dressing and who reports misorders buttons or forgetting details, this would also be a yes in item 17 (trouble in dressing or self-care). In other words, it is possible for someone to have some physical limitations but to also have problems with cognitive function that interfere with these basic activities of daily function, and the functional problems related to cognitive decline would also be scored a 1 or yes. Again, it is up to you to provide as much information and probes as possible for the informant to make their own decision about whether the participant is able to perform these activities.
 - If "Yes" on any items 1-20, proceed with asking Items 21-25.
- Item 21-22. Ask: "***Who first noticed something wrong?***" Record the relationship of the person to the participant and the circumstances surrounding this first notice of problems.
- Item 22. "Old Self" - please add "***when these problem(s) [was/were not] present***".
- Item 23-25. These are self-explanatory; remember to record verbatim "*what cause was given*".
- Items 26(a-1) Stroke Questions. These questions are needed to gather more detailed information about stroke status. Questionnaires such as this one have been used in prior research as a practical, reliable, and valid method of determining stroke status. These questions are entirely self report and can be asked of their informant.
- Item 27: Alcohol problems. This question pertains to significant persistent alcohol use, such as 3 or more drinks per day OR if alcohol use ever affected ability to function in personal, family or professional life.
- Items 28-29: Depression.
 - *For the following questions, I would like you to answer Yes or No.*
 - . . . you can also add , "*did you/participant feel sad, depressed, blue or down in the dumps?*"
 - Based on the participant's answers, each item will be marked as Yes or No.
 - During this interview, a participant may not answer a question with yes or no, but will describe their feelings in more detail or recall an event. Write down what the participant says. Then use your interviewing skills to encourage the participant to choose yes or no.
 - Sometimes the participant will not narrow their answer to a yes or no after these types of prompts. In these cases, write down what the participant tells you in the margins of the page. This will allow discussion of "borderline" answers with the adjudication team. A general rule is that items will be marked as Yes even if the participant has the symptom only some of the time or if they tell you that they the symptom is mild in intensity; however, if the participant does not give you a yes or no answer, you should write down their response as fully as possible in the margins in order to facilitate discussion.
- Questions 30-35. Self-explanatory.
- Question 36-37. Self-explanatory.
- Question 38. This question is not asked of the participant, but is to be answered by the Interviewer. This question is based on the judgment of the informant's responses to this questionnaire. Please rate the reliability of the responses as "very reliable", "fairly reliable", "not very reliable" or "don't know". Please try to give a response and limit the use of don't know.

General Instructions:

1. There is no examiner script for this form because the questions are to be asked verbatim. You do not need to introduce the questions because you have already been asking questions about medical history.
2. If the participant does not understand the question or needs it to be rephrased, you may do so without changing the meaning of the question. If you must rephrase a question in order to clarify its meaning, write down verbatim how you rephrased the question in the notes field on the form.
3. Because subjects and informants may not be sophisticated regarding their medical diagnoses, the interviewer may need to ask a series of additional questions (probes) to be sure the information is as accurate as possible. If they are unsure as to whether they received a formal diagnosis of stroke, call them back at a future time.

DECEDENT PROXY INTERVIEW (PANEL 18-II)

The Decedent Proxy Interview (Panel 18-II) is a short interview that is to be administered to the Designated Family Reporter/Proxy 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. In 2015, a Morbidity and Mortality committee was convened to discuss how to adjudicate cause of death. Per this committee, the DPI was updated to gather more information on specific hospitalizations and to ask all family members for a narrative about the death of the participant (Q21a).

An introductory script and notes to the interviewer pertaining to specific questions are included directly on the form.