

## CHAPTER 15

### LIFE COGNITION ASSESSMENT PROCEDURES

<b>15.1</b>	<b>Introduction.....</b>	<b>15-2</b>
<b>15.2</b>	<b>Guidelines for Cognitive Test Administration.....</b>	<b>15-2</b>
	15.2.1 Standardized Administration.....	15-2
	15.2.2 General Instructions.....	15-3
	15.2.3 Additional Suggestions for Preserving Standardization	15-3
<b>15.3</b>	<b>Cognitive Assessment Testing Order .....</b>	<b>15-4</b>
	15.3.1 Screening Visit 1 .....	15-4
	15.3.2 Screening Visit 2 .....	15-4
	15.3.3 Follow-up Assessment – 18 Month Visit .....	15-4
	15.3.4 Follow-up Assessment – 24 Month Visit.....	15-5
	15.3.5 Follow-up Assessment – 30 Month Visit.....	15-5
	15.3.6 Follow-up Assessment – PIV .....	15-5
<b>15.4</b>	<b>Materials Needed for Testing.....</b>	<b>15-5</b>
<b>15.5</b>	<b>Instructions for Specific LIFE Cognition Assessments .....</b>	<b>15-6</b>
	15.5.1 Introducing the Test Battery.....	15-6
	15.5.2 Modified Mini-Mental Status Exam (3MSE) .....	15-6
	15.5.2.1 Specific Instructions for the 3MSE.....	15-7
	15.5.3 Hopkins Verbal Learning Test – Revised (HVLT-R).....	15-12
	15.5.3.1 Specific Instructions for the HVLT-R.....	15-12
	15.5.4 Boston Naming Test.....	15-14
	15.5.5 Trail Making Tests A & B.....	15-15
	15.5.5.1 Specific Instruction for the Trails A & B.....	15-16
	15.5.6 Category Fluency Animals.....	15-18
	15.5.7 Digit Symbol Substitution Test (DSST).....	15-19
	15.5.7.1 Specific Instruction for the DSST .....	15-19
	15.5.8 Modified Rey-Osterreith Complex Figure (Rey-O).....	15-20
	15.5.8.1 Specific Instruction for the Rey-O.....	15-20
	15.5.9 Functional Assessment Questionnaire.....	15-22
	15.5.9.1 Specific Instructions for the FAQ.....	15-22

15.5.10	Telephone Interview of Cognitive Status (TICS).....	15-22
15.5.10.1	Specific Instructions for the TICS.....	15-22
15.5.11	Dementia Questionnaire (DQ).....	15-25
15.5.11.1	Specific Instructions for the DQ.....	15-25
15.5.12	E-Prime Computerized Tests.....	15-30
15.5.12.1	Start-Up Procedures .....	15-30
15.5.12.2	Troubleshooting Tips .....	15-30
15.5.12.3	Specific Instructions for the E-Prime Test Battery.....	15-32
15.5.12.3.1	Flanker Test .....	15-34
15.5.12.3.2	The One-back Test .....	15-36
15.5.12.3.3	The Two-back Test .....	15-41
15.5.12.3.4	The Task-Switching Test .....	15-46
15.6	Data Entry and Data Upload for Cognitive Assessments.....	15-50
15.7	Certification Process for Field Site Cognitive Assessors .....	15-50
15.8	Dementia Adjudication at Follow-Up.....	15-51

## CHAPTER 15

### LIFE COGNITION ASSESSMENT PROCEDURES

#### 15.1. INTRODUCCION

In order for LIFE to capture cognitive data that are valid and useable, it is imperative that technicians follow a standardized procedure when administering and scoring the test battery. The way in which the testing is administered to a participant can affect the validity of the responses to items. Therefore, it is important that the technician adhere strictly to the written guidelines and the following general tips for test administration.

#### 15.2. GUIDELINES FOR COGNITIVE TEST ADMINISTRATION

##### 15.2.1 Standardizing Administration

Variability in administration introduces bias in data collection. Testing guidelines are established so that each technician administers the instruments in the same way. The technician's presence should not bias the participant's perception or response to a question, and different technicians should be able to obtain the same responses from the same participant. Technicians should think of themselves as part of the instrumentation. To enhance standardization:

- i) Do not provide either verbal or non-verbal responses that could influence the participant's responses. For example, do not convey surprise, pleasure or disapproval to any answer. The technician's role is to obtain honest, uninfluenced responses to the questions.
- ii) Be thoroughly familiar with the instruments before administering them. This ensures that participant questions or concerns can be easily addressed. Practicing test administration with someone who is pretending to be a participant helps to reduce the mechanical style that sometimes results from reading unfamiliar material.
- iii) Convey a sense of impartiality. Be gracious and adaptable to all participants regardless of whether their dress, appearance, style of speech or personal preferences is consistent with your values and preferences.
- iv) Read all directions to the participant verbatim, both sample and actual test directions.
- v) Administer all tests in the order in which they are presented. **The sequence of the tests is important.**
- vi) Record the participant's responses on the instrument as they are given. Audiotape each test administration. Never depend on your memory to mark the participant's choices.
- vii) Keep explanations to a minimum. Avoid interpreting or paraphrasing instructions or interview questions. It is easy to alter the meaning in this way.
- viii) Offer generic phrases of encouragement during and between tests but do not offer any information on the correctness of a particular response (including nonverbal communication like nodding or shaking your head). If the participant is persistent, explain that you are not permitted to give feedback.

- ix) Do not offer any assistance in completing tasks that is not specifically permitted in the instructions.
- x) Do not place score sheets where the participant can see them. Use a clipboard or other device to shield the results.
- xi) Never suggest an answer or disagree with a response. The technician's role is to obtain and record the **participant's** responses.

### 15.2.2 General Instructions

- i) Prior to each administration, review the test materials to refresh your memory as to the correct procedures.
- ii) Choose a quiet area in the clinic to conduct the cognitive testing.
- iii) Put a sign on the door such as **"Quiet Please: Testing in Process"** to minimize interruptions.
- iv) If there is a phone in the room, turn it off. If the participant has a cell phone or pager, please ask them to turn it off or silence it.
- v) Assemble testing materials and equipment. Check your equipment (tape recorder and stopwatch) to make sure the batteries are good. Keep extra batteries in the testing area.
- vi) Highlight the administration booklet to remind you to do things such as check time or remember to give a prompt.
- vii) Have a relaxed and friendly manner which will help put the participant at ease and convey the importance of the testing. Spend a few minutes putting the participant at ease with light conversation.
- viii) Be patient and polite. Convey a sense that the participant's answers are important. Do not rush.
- ix) Observe the participant for signs of strain or stress (e.g., becomes nervous, puts less effort into tasks, and starts making excuses). Try to help the participant relax with generic reassurances and encouragement (e.g., "you're doing fine").
- x) Reassure the participant, at any point in the interview that his/her answers will be kept confidential.
- xi) Family members or friends may accompany the participant to the clinic. They should not be present during test administration. Explain to the friend or family member the necessity of providing privacy and confidentiality, and be prepared to suggest a place where they can wait comfortably during testing.

### 15.2.3 Additional Suggestions for Preserving Standardization

Use these specific words to offer as encouragement for ALL participants:

- i) ***"Just do the best that you can. As long as you do the best that you can, you are doing what we want you to do."***
- ii) ***"These tasks are designed so that no one gets all the answers correct. As long as you are doing the best that you can, you are doing what we want you to do."***

## **15.3 COGNITIVE ASSESSMENT TESTING ORDER**

### **15.3.1 Screening Visit 1 – Paper/Pencil Tests**

- ii) Hopkins Verbal Learning Test (HVLT) – Trials 1, 2, & 3
- iii) Modified Mini-Mental State Exam (3MSE)
- iv) Digit Symbol Substitution Test (DSST)
- v) Rey-Osterrieth Complex Figure (Rey-O)
- vi) HVLT – Trial 4 and Delayed Recognition

### **15.3.2 Screening Visit 2 – E-Prime Computerized Tests**

- i) Flanker Task
- ii) N back (one back and two back)
- iii) Task switching

### **15.3.3 Follow-up Assessment – 18 Month Visit**

- i) Flanker Task
- ii) N back (one back and two back)
- iii) Task switching

### **15.3.4 Follow-up Assessment – 24 Month Visit**

- i) Modified Mini-Mental State Exam (3MSE)
- ii) Hopkins Verbal Learning Test (HVLT) – Trials 1, 2, & 3
- iii) Boston Naming Test
- iv) Trail Making Test A & B
- v) Category Fluency - Animals
- vi) Digit Symbol Substitution Test (DSST)
- vii) Rey-Osterrieth Complex Figure (Rey-O)
- viii) HVLT – Trial 4 and Delayed Recognition

### **15.3.5 Follow-up Assessment – 30 Month Visit (if not performed at the 18 Month Visit)**

- i) Flanker Task
- ii) N back (one back and two back)
- iii) Task switching

### **15.3.6 Follow-up Assessment – Post Intervention Visit**

- i) Modified Mini-Mental State Exam (3MSE)
- ii) Hopkins Verbal Learning Test (HVLT) – Trials 1, 2, & 3
- iii) Boston Naming Test
- iv) Trail Making Test A & B
- v) Category Fluency - Animals
- vi) Digit Symbol Substitution Test (DSST)
- vii) Rey-Osterrieth Complex Figure (Rey-O)
- viii) HVLT – Trial 4 and Delayed Recognition

## 15.4 MATERIALS NEEDED FOR TESTING

Have in place and arrange all of the following at each test session:

- Paper test forms: Hopkins VLT, 3MSE, DSST, Rey-O, Trail Making Tests A and B, Boston Naming Test, Category Fluency Animals
- Digital recorder
- Sharpened pencils
- Clipboard
- Stopwatch
- Wristwatch
- Laminated testing sheets: 3MSE “Close Your Eyes”, Pentagon Drawing, Rey-O figure
- Boston Naming Test Stimulus book
- Digit Symbol Substitution Test Scoring Template
- Extra paper
- Batteries for digital recorder
- Laptop computer and power cord for E-Prime testing
- Computer files for exporting data to Coordinating Center
- Laminated cards for computer tests: examples of each test, place cards for Z and M keys
- Dry erase pen for writing on laminated examples
- Stickers for M and Z computer keys

## 15.5 INSTRUCTIONS FOR SPECIFIC LIFE COGNITION ASSESSMENTS

To begin the cognitive test session, make sure the participant is comfortable. Ask the participant for permission to record the session. Explain that the purpose of the recording is to ensure that the test administration and scoring are done correctly and consistently across all sites. There will be no identifying information on the recording. *Write the participant Acrostic, Visit Code, Date and Interviewer Number on CD.*

Before testing ask the participant if s/he wears glasses or uses a hearing aid? If so, does s/he have them?

If the participant has any difficulty completing any of the tests, make a note of the difficulty on the Visit Checklist.

### 15.5.1 Introducing the Test Battery

**Examiner:** ***“In this part of the visit, I am going to have you do a series of tasks that challenge your memory and other thinking abilities. You will not get every item correct, so don’t worry about it. Just relax and do the best you can on each and every one. I will instruct you before each task so you will know what to do. Some of the tests will be timed so you will have to do them as quickly as you can. Shall we get started now?”***

### 15.5.2 Modified Mini-Mental Status Exam (3MSE)

**Description:** This is an expanded version of the original Folstein MMSE designed to increase the standardization, sensitivity, and specificity of the test as

a screen for dementia. The 3MSE assesses a broader variety of cognitive functions, covers a wider range of difficulty levels, and enhances the reliability and validity of the scores.

**Materials Needed:**

- Test Administration Booklet
- Pencil with eraser
- Stop watch
- Extra paper
- “Close your eyes” card
- Pentagon card

**15.5.2.1 Specific Instructions for Administering the 3MSE**

- i) Technicians should be thoroughly familiar with the testing procedures
- ii) Give at least 2 seconds for a response, but do not converse or offer extra help.
- iii) If the participant says, “I don’t know” or is unable to give an answer, prompt once with a statement such as “Please try,” or “Give it a try.”
- iv) When the participant gives an incorrect answer, the technician should score accordingly and proceed to the next item.

**Date and Place of Birth: Question 1**

- i) Measures long term memory.
- ii) Fill in the month, day, and year reported by the participant; convert the month into numerical format.
- iii) If the participant gives a partial answer regarding place of birth, ask for the missing information.
- iv) If an unrelated answer is given (e.g., hospital name) clarify the question by telling the participant that you are looking for the city/town and state or country in which he/she was born.
- v) If the participant gives a response, record the city/town and state/country and circle “answer given.”
- vi) SCORING NOTE: This question is repeated at the end of the test to verify the participant’s response since the technician will have no source for determining the accuracy of the response. If the participant’s response is the same for both questions, the answer is considered correct.

**Registration: Question 2**

- i) Say the three words distinctly at the rate of 1-2 seconds per word.
- ii) If the participant repeats after each word is read by the technician, at the end of the presentation of all three words say, “Tell me the three words again” and mark the score according to the responses to this request.
- iii) The exact form of the word must be repeated. Do not accept “shirts” for “shirt” or “honest” for “honesty.”
- iv) Only score the first trial.

- v) Record the number of presentations necessary for the participant to repeat all 3 words (up to six – for a total of seven presentations) on line 2d.

#### **Mental Reversal: Questions 3 & 4**

- i) This question has two parts: counting backwards from 5 to 1 and spelling WORLD backwards.
- ii) For each part, ask the participant to do the forward version first; coach once when needed.
- iii) Give credit for self-corrections.
- iv) If the participant cannot count forward to 5, prompt with “Say 1, 2, 3, 4, 5” at the rate of 1.5 seconds per number.
- v) If the participant cannot spell “W O R L D” forward, prompt with “It is spelled W O R L D” at the rate of 1.5 seconds per letter.

#### **First Recall of Three Words: Question 5**

- i) The participant may repeat the words in any order.
- ii) For each word not readily repeated, provide the category followed by multiple choices when necessary. Do not wait more than 3 seconds for spontaneous recall and do not wait more than 2 seconds after giving the category before providing the next level of help. If the category cue is needed, say (for example), “It was ‘Something to wear.’”
- iii) If the participant gives an incorrect answer in the correct category (e.g., “socks” or “coat” instead of “shirt”), provide the three alternatives for them to choose from and score 1 when the choice is correct.
- iv) If the participant repeats an incorrect form of the correct word, (e.g., “shirts” for “shirt”) score as correct word/incorrect form. In these cases it is very important to repeat the word with the correct ending back to the participant for the subsequent recall.
- v) If the participant does not report all 3 words without help (i.e., total score on 5a-5c is <9), say the 3 words once more before proceeding with Question 6.

#### **Temporal Orientation: Question 6**

- i) Ask for the date. Fill in the month, day, and year reported by the participant. Convert the month into numerical form.
- ii) Ask the day of the week. Write the response only if it is incorrect.
- iii) Ask the season of the year. Write the response only if it is incorrect.
- iv) Since distinctions between seasons can be difficult during certain months, the following table has been created. For months with two seasons listed, either answer is correct. Write the response only if it is incorrect.

Month	Correct Response
January	Winter
February	Winter
March	Winter or Spring
April	Spring
May	Spring



June	Spring or Summer
July	Summer
August	Summer
September	Summer or Fall (Autumn)
October	Fall (Autumn)
November	Fall (Autumn)
December	Fall (Autumn) or Winter

### **Spatial Orientation: Question 7**

- i) Write the response only if it is incorrect.
- ii) Question 7.2: If the participant indicates that they do not know the name of the county where the clinic is located because they do not live there, you may ask "What county do you live in?" and if known accept that as a correct response. However, if s/he gives an incorrect answer to the county, do NOT prompt with "What county do you live in?"
- iii) Question 7.4 assumes that the test is being administered in a clinic setting. When the correct answer is not among the three alternatives, substitute the correct response for the middle alternative (store).
- iv) If the participant responds that neither "clinic", "store" nor "home" is the correct answer, ask them to make the best choice out of the three options.

### **Naming: Question 8**

- i) This set of questions tests whether or not the participant can promptly name the two objects and the five body parts.
- ii) Correct responses for 8.2: watch, wrist watch, or timepiece
- iii) If using an object other than a watch or pen, write what is being used on the form. You should choose a very common object that all participants will know, such as a ring, glasses, paper, etc.
- iv) Correct responses for each body part are:
  - a) Forehead or brow
  - b) Chin
  - c) Shoulder or shoulders
  - d) Elbow or elbows
  - e) Knuckle or Knuckles
- v) If the participant cannot name the item within 2 seconds or gives an incorrect answer, do not help or question again.
- vi) If the participant gives a scientific or medical version of the name for any of the body parts, ask him/her to provide the common name.

### **Four Legged Animals: Question 9**

- i) Record each animal named in the spaces provided.
- ii) Discontinue after 30 seconds. Record the total number of correct responses.
- iii) If the participant gives no response in 10 seconds and there are still at least 10 seconds remaining, gently remind them (only once): "What (other) animals have four legs?"

- iv) The first time an incorrect answer is provided, say “I want four-legged animals.” Do not correct for subsequent answers.
- v) Accept marginal cases such as:
  - a) Monkey
  - b) Chimp
  - c) Baboon
  - d) Kangaroo
- vi) Different names for the same animal of different age or sex count as one animal:
  - a) Kitten/cat
  - b) Puppy/dog
  - c) Deer/doe
- vii) Other oddities:
  - a) A sea lion does not have four legs
  - b) A seal does not have four legs
  - c) A platypus is acceptable
- viii) A set of abbreviations may be helpful for writing the animal names quickly.

#### **Similarities: Question 10**

- i) Question is designed to measure abstract or conceptual thinking. In general, 2 points are given for conceptual similarities, which are primarily pertinent for both members of the pair.
- ii) Always accept the first answer given.
- iii) If two concepts are given simultaneously (i.e., within the first statement provided back by the participant), score the higher value of the two concepts.
- iv) If the initial response is scored “lesser correct answer” or “error/refused” coach the participant by saying “An arm and a leg are both limbs or extremities” to reinforce the correct answer.
- v) **Coach only for Question 10.1.** No other prompting or coaching is allowed.

#### **Repetition: Questions 11 & 12**

- i) Pronounce the individual words distinctly but with normal tempo of a spoken sentence.
- ii) No credit is given if the participant misses the “s”.

#### **Read and Obey: Question 13**

- i) Hold up the card and say “Please do this.”
- ii) It is acceptable for the participant to read the sentence aloud. The participant is only scored on whether he/she closes his/her eyes.
- iii) As soon as the participant closes his/her eyes say, “Open.”

#### **Writing: Question 14**

- i) Allow a maximum of 1 minute after the first reading of the sentence for scoring the task.

- ii) If the participant is still working at the end of 1 minute, allow them to complete the task for the sake of maintaining rapport and morale. Mark the 1 minute point on the product and do not credit for parts finished after 1 minute.
- iii) Assign 1 point for each correct word, but no credit for "I". Mark as an error if there are spelling errors or incorrect mixed capitalizations (all letters printed in uppercase is permissible).
- iv) Observe which hand the participant uses to write and record on the form. This will be used in Question 16. If this question is not performed, ask the participant if he/she is right or left handed.

#### **Copying Two Pentagons: Question 15**

- i) Allow a maximum of 1 minute for the drawing.
- ii) If the participant is still working at the end of 1 minute, allow them to complete the task for the sake of maintaining rapport and morale. Mark the 1 minute point on the product and do not credit for parts finished after 1 minute.
- iii) Do not penalize for self-corrected errors, tremors, minor gaps (<¼ inch), or overshoots.
- iv) When gaps are found in the drawing, they are permissible if the shape of the pentagon can be perceived.

#### **Three Stage Command: Question 16**

- i) Refer back to Question 14.6 to determine whether the participant is right or left handed.
- ii) Do not repeat any part of the command. If the participant requests a portion of the command be repeated, and it is felt appropriate to oblige for the sake of maintaining rapport, score according to the response(s) executed prior to repeating the command.
- iii) If the participant reaches for the paper right after hearing the first portion of the command, the technician should move the paper away from the participant so it is out of reach and continue to state the next two parts of the command without interruption.
- iv) The participant may use both hands to fold the paper.
- v) The participant may hand back the paper with either hand.

#### **Second Recall of Three Words: Question 17**

- i) Administer this question even if the participant did not recall the words in Question 5.
- ii) Words may be repeated in any order.
- iii) Provide categories as needed, as in Question 5.

#### **Validation of Birthplace: Question 18**

- i) Ask this question only when a response was given in Question 1.1 and 1.2.
- ii) Score the response by checking against the response in Question 1.1 and 1.2.

### **Special Problems: Question 19**

- i) If any physical/functional disabilities or other problems exist which cause the participant difficulty in completing any of the tasks, mark the box coded “yes” and record the nature of the problem.
- ii) If no special problems were noted, check “no.”

### **15.5.3 Hopkins Verbal Learning Test - Revised (HVLT-R)**

**Description:** The HVLT-R measures immediate memory span, provides a learning curve, reveals learning strategies or their absence, and short-term and longer-term retention. It consists of three presentations with recall of a 12-word list, a delayed recall trial (at least 20 minutes after Trial 3), and a delayed recognition.

#### **Materials Needed:**

- Test Administration Forms
- Pen/pencil
- Watch or clock to note the time

#### **15.5.3.1 Specific Instructions for Administering the HVLT-R**

On Page 3 of the HVLT form, insert the participant Acrostic, Interviewer number, Visit Code, and Date. Do not write the participant’s name, sex, or age on the form.

#### **Part A – Free Recall: Trial 1**

Examiner: ***“I am going to read a list of words to you. Listen carefully, because when I am through, I’d like you to tell me as many of the words as you can remember. You can tell them to me in any order. Are you ready?”***

Read the words at the rate of one word every 2 seconds.

Examiner: ***“OK. Now tell me as many of those words as you can remember.”***

- i) Write the words the participant recalls on the form.
- ii) Record the responses verbatim (including repetitions and intrusions) and say nothing to the participant about words not on the list.
- iii) **There is no time limit for each recall trial.** However, if the participant does not produce any words for 10-15 seconds, ask the participant if he/she can remember any more words.
- iv) If not, move on to trial 2. Later, you can score the number of words that were correctly repeated.
- v) Total the number of correctly recalled words. Minor errors in pronunciation and plurals are considered correct.

#### **Part A – Free Recall: Trial 2**

Examiner: ***“Now we are going to try it again. I am going to read the same list of words to you. Listen carefully, and tell me as many of the words as***

***you can remember, in any order, including the words you told me the first time.”***

- i) Write the words the participant recalls on the form.
- ii) Record the responses verbatim (including repetitions and intrusions) and say nothing to the participant about words not on the list.
- iii) **There is no time limit for each recall trial.** However, if the participant does not produce any words for 10-15 seconds, ask the participant if he/she can remember any more words.
- iv) If not, move on to trial 3. Later, you can score the number of words that were correctly repeated.

### **Part A – Free Recall: Trial 3**

**Examiner:** ***“I am going to read the list one more time. As before, I’d like you to tell me as many of the words as you can remember, in any order, including all the words you’ve already told me.”***

- i) Write the words the participant recalls on the form.
- ii) Record the responses verbatim (including repetitions and intrusions) and say nothing to the participant about words not on the list.

**There is no time limit for each recall trial.** However, if the participant does not produce any words for 10-15 seconds, ask the participant if he/she can remember any more words.

**IMPORTANT:** **Do not** tell the participant that recall of the words will be tested later.

### **Part B – Delayed Recall**

HVLT-R Part B – Delayed Recall should be administered at least 20 minutes after Part A of the HVLT-R. **DO NOT READ THE WORD LIST AGAIN.**

**Examiner:** ***“Do you remember that list of words you tried to learn before? Tell me as many of those words as you can remember.”***

There is no time limit for the recall trial. However, if the participant does not produce any words for 10-15 seconds, ask the participant if he/she can remember any more words.

If the participant cannot remember the list, say ***“It was the list that I read to you three times and you were asked to recall the list each time.”***

### **Part C – HVLT-R Delayed Recognition**

**Examiner:** ***“Now I’m going to read a longer list of words to you. Some of them are words from the original list, and some are not. After I read each word, I’d like you to say “Yes” if it was on the original list or “No” if it was not. Was [word] on the list?”***

- i) Read the words from the top of the columns down.
- ii) Circle either the “Y” (Yes) or “N” (No) next to each word to indicate the participant’s response.
- iii) Guessing is allowed.

Total the scores as listed on the form. Words that are printed in capital letters in unshaded boxes are the true-positive words (words from the original list) to which the participant should say “Yes.” Lower-case words in lightly shaded boxes are semantically-related words to which the participant should say “No.” Lower-case words in darker shaded boxes are semantically-unrelated words to which the participant should say “No.”

Total the true-positive responses and enter on the line provided.

Total the semantically-related false positives (the participant responded “Yes”) on the line provided.

Total the semantically-unrelated false positives (the participant responded “Yes”) on the line provided.

Add the semantically-related and semantically-unrelated false positives and enter the total number of false-positive errors on the line provided.

**Do not** complete the box with *Raw Score* or *T Score*.

#### 15.5.4 **The Boston Naming Test – 15 Item**

##### **Materials Needed:**

- Boston Naming Test Stimulus book
- Test Administration Form

##### **Administration**

Say to the participant: ***“Now I am going to show you some pictures and I want you to say the name of each picture.”***

- Present the 15 line drawings in the Boston Naming Test Stimulus book to the participant in order, beginning with the first one. For each picture, ask the following until the participant begins to name the pictures on his/her own: ***“What is the name of this object?”*** or ***“Can you name this?”***
- Allow a maximum of 20 seconds for each picture. If the participant cannot name the object spontaneously (“I don’t know”) or gives a response that may be a *misperception* of the picture, give the cue printed on the BNT form which is printed in parentheses under the response line for each item. For example, if the response to picture #9 is “horse” say, “It looks like that but the artist meant to draw a *mythical animal*.” Allow up to 20 seconds after giving the cue, then proceed to the next picture.
- Do not give a prompt for an incorrect response. For example, “dice” is not a correct response for “dominoes” and it does not warrant a prompt. Score “dice” as incorrect.
- The cues are as follows:

##### **Picture**

Pretzel  
Seahorse  
Rhinoceros  
Acorn

##### **Cue**

something to eat  
an ocean animal  
an animal  
it comes from a tree

Dominoes	a game
Pelican	a bird
Stethoscope	used by doctors and nurses
Muzzle	used on dogs
Unicorn	mythical animal
Asparagus	something you eat
Scroll	a document
Tongs	a utensil
Sphinx	it's found in Egypt
Trellis	used in a garden
Palette	artists use it

- Use a prompt for responses that indicate only a part of the picture. For example, for item #8 if the respondent says, “dog” you should point to the picture with your pencil or pen and outline the item. Score as correct only if the participant names the item (‘muzzle’).
- A non-specific prompt can be used if the response is too general. For example, if the response to the “dominoes” item is “game”, say “***Is there another name for that?***” You may NOT ask “Isn’t that a special kind of game?” If none is given, score as incorrect.
- If the participant makes an error but corrects it spontaneously, score the response as correct.

### Scoring

- Give 1 point for each correct response given spontaneously. Give 1 point for a correct response following the cue. Give 0 points for incorrect responses whether or not a cue is given. The participant’s total BNT score is the sum of points (max = 15).
- In general, a more specific correct response is acceptable. For example, a response of “horse fish” to the “seahorse” item is correct.
- Regional terms and synonyms, if verified, are counted as correct. Acceptable alternate responses are provided in parentheses next to the item on the score sheet.
- If you are in doubt as to whether a response is correct, a misperception, or incorrect do your best during the test and then please email or call the LIFE Cognition Coordinating Center for a ruling.

### 15.5.5 Trail Making Test (Parts A & B)

**Description:** The Trail Making Tests assess processing speed, attention, sequencing, mental flexibility and visual-motor skills.

#### Materials Needed:

- Test Administration Form and Participant Sample Pages and Worksheets
- Stopwatch
- Pencil

### 15.5.5.1 Specific Instructions for Administering Trail Making Test

- i) Read instructions verbatim
- ii) Do not proceed with the test until the participant understands and correctly completes the sample form.
- iii) If the participant is unable to complete the sample item, repeat up to 3 times. If s/he still cannot complete the sample, do not administer the test. Record 5 minutes (300 seconds) for the total time and note the participant was unable to complete the sample. (See trouble shooting table line 3 for specific instructions of administration when a participant does not understand instructions).
- iv) After successful completion of the sample trial, give the participant the test page.
- v) Repeat the test instructions, reading verbatim, as you did for the sample trial.
- vi) Maximum testing time = 5 minutes (300 seconds) for each test – Parts A & B.
- vii) Observe the participant closely in order to catch errors as soon as they are made. As unobtrusively and quickly as possible make a mark on the incorrect line and provide immediate feedback. (***“You were correct up to here [point to last correct circle]. Remember to go in the correct order.”***). Do not stop the stopwatch.
- viii) Self corrections are allowed and should not be counted as an error. If the participant self corrects, make a note of the self correction on the participant worksheet.
- ix) If the participant touches or goes through an incorrect circle on their way to the intended circle, it should be counted as an error. You should immediately redirect them back to the last correct connection and say ***“You were correct up to here. Remember to go in the correct order.”*** You should also remind the participant to only touch the intended circles.
- x) Record time to complete the test as **MINUTES:SECONDS** – rounding to the nearest second.
- xi) Record the number of errors.
- xii) Discontinuation Rule for A & B: If the participant makes 5 errors or reaches 5 minutes (300 seconds), discontinue the test. Total time should be scored as 5 minutes (300 seconds) and 5 errors.
- xiii) For specific “troubleshooting” questions, please refer to the table below.

#### Part A

##### **Administration**

- Place the Part A Sample form in front of the participant.

Examiner: ***“There are numbers in circles on this page. Please take the pencil and draw a line from one number to the next, in order. Start at 1 (point to the number), then go to 2 (point to the number), then go to 3 (point to the number) and so on. Please try not to lift the pencil as you move from one circle to the next. Work as quickly as you can. Ready? [pause for a response] Begin.”***



- If the participant makes an error, mark through the line and go back to the point at which the error was made and say, for example, ***“You were at number 2. What is the next number?”*** Wait for the participant’s response and say, ***“Please start here and continue.”***
- If the participant completes the sample correctly, go to Test A. **Repeat the instructions given for the sample.** Start timing as soon as the instruction is given to begin.
- Stop timing when Trail A is completed or when the maximum time (5 minutes) is reached.
- Allow a maximum of 5 minutes (300 seconds) for the test. YOUR STOPWATCH SHOULD READ 5:00. Be careful not to confuse 300 on the stopwatch (3 minutes) with 300 seconds (5 minutes).

### Scoring

Record the time as MINUTES:SECONDS (rounding to the nearest second) and number of errors on the Trails form.

### Part B

#### Administration

- Place the Part B sample form in front of the participant.

Examiner: ***“There are numbers and letters in circles on this page. Please take the pencil and draw a line, alternating in order between the numbers and letters. Start at number 1 (point to the number), then go to the first letter, A (point to the letter), then go to the next number, 2 (point to the number) and then to the next letter, B (point to the letter), and so on. Please try to not lift the pencil as you move from one circle to the next. Work as quickly as you can. Ready? [pause for a response] Begin.”***

- If the participant makes an error, mark through the line and go back to the point at which the error was made and say, for example, ***“You were at number 2. What is the next letter?”*** Wait for the participant’s response and say, ***“Please start here and continue.”*** If the participant completes the sample correctly, go to Test B. **Repeat the instructions given for the sample.** Start timing as soon as the instruction is given to begin.
- Stop timing when Trail is completed or stop participant when maximum time is reached or when 5 errors have been made.
- Allow a maximum of 5 minutes (300 seconds) for the test. YOUR STOPWATCH SHOULD READ 5:00. Be careful not to confuse 300 on the stopwatch (3 minutes) with 300 seconds (5 minutes).

### Scoring

Record the time as MINUTES:SECONDS (round to the nearest second) and number of errors on the Trails form.

**Troubleshooting Table**

<b>Problem</b>	<b>Solution</b>
Participant lifts pencil	Instruct the participant to keep the pencil in contact with the paper and move on to the next circle
Participant asks for feedback	Instruct the participant to finish the test; encourage to continue but do not provide qualitative feedback
Participant does not understand directions	Repeat directions as necessary. If the participant still does not understand, guide the participant's hand with the eraser of the examiner's pencil and verbalize the instructions as you move the participant's hand through the practice items, then have the participant attempt again. If it is evident that the participant cannot complete the test, enter a maximum score of 5:00 (300 seconds) and 5 errors.
Participant lifts the paper	Instruct the participant to keep the paper oriented vertically
Participant attempts self-correct	Instruct participant to put a dash through their line and continue from the last number. Do not count self-corrections as errors.
Participant becomes inattentive or tries to leave	Ask the participant to finish the test first
Participant starts with the wrong circle	Tell the participant that they started with the wrong circle and point to circle 1
Participant skips a circle or connects the wrong circle	Return the participant to the last correct circle and say "You were at number/letter XX. What is the next number/letter?" Wait for the participant's response and say, "Please start here and continue."

**Adapted from** "Administration and interpretation of the Trail Making Test" **Christopher R Bowie & Philip D Harvey, *Nature Protocols* 1; 2277 - 2281 (2006).**

### **15.5.6 Category Fluency – Animals**

**Description:** This task requires the participant to name as many animals as possible in 60 seconds (Note: DIGITAL STOPWATCH WILL READ 1:00). It assesses verbal fluency.

#### **Materials Needed:**

- Test Administration Form
- Stopwatch

#### **Administration**

Examiner: ***"I am going to give you a category and I want you to name, as fast as you can, all of the things that belong in that category. For example, if I say "articles of clothing," you could say 'shirt,' 'tie,' or 'hat'. Can you think of other articles of clothing?"***

- Allow the participant to produce 2 or 3 responses. If the responses are not articles of clothing, you can say, ***“No, X is (are) not an article(s) of clothing. You could have said ‘shoes’ or ‘coat’ since they are articles of clothing.”***

Then, read the following instructions: ***“Now, I want you to name things that belong to another category: Animals. You will have one minute. I want you to tell me all the animals you can think of in one minute. Ready? Begin.”***  
Start timer.

- Record the participant’s responses, using abbreviations if necessary. Review the audio recording afterwards if the participant names animals faster than you are able write.
- One prompt is permitted (***“Tell me all the animals you can think of.”***) if the participant makes no response for 15 seconds or quits (e.g., “I can’t think of any more”). Stop the participant at the end of one minute (DIGITAL STOPWATCH SHOULD READ 1:00).

### **Scoring**

Give one point for each animal named within one minute. Imaginary, extinct or magic animals are permissible as are names of different aged animals (puppy-dog). Proper names, repetitions or variations (e.g. ‘baby dog’ and ‘puppy’) are not allowed. Different breeds within the same family are acceptable, e.g., poodle, beagle. However, proper names (e.g., Butch) or different names for the same animal (e.g., little dog and puppy) are considered the repetitions and would receive only 1 point.

## **15.5.7 Digit Symbol Substitution Test (DSST)**

**Description:** The DSST assesses sustained attention, concentration, visuo-motor coordination and motor persistence. It is part of the Wechsler Adult Intelligence Scale-Third Edition (WAIS-III). The test consists of 7 rows containing a total of 140 small blank squares, each of which is paired with a randomly assigned number from one to nine. Above these rows is a printed key that pairs each number with a different symbol. The participant is asked to fill in the blank spaces with the symbol that is paired to the number as quickly as possible for **2 minutes**.

### **Materials Needed:**

- Test administration form and participant worksheet
- Stopwatch
- Pencils
- Scoring Template

### **15.5.7.1 Specific Instructions for Administering and Scoring the DSST**

- i) Read instructions verbatim.

- ii) Do not proceed with the test until the participant understands and correctly completes the seven sample items. Instructions can be repeated up to 2 times.
- iii) Begin timing once the sample and instructions are completed.
- iv) **Testing time = 2 minutes.**
- v) Boxes must be done in sequence (left to right). It is important that you position yourself beside the participant so that you can observe him/her closely. Do not sit on the participant's dominant side (if they are right handed, sit on their left).
- vi) If the participant begins working out of sequence (out of sequence means clustering or grouping, e.g., doing all of the 1's), redirect him/her **only** on the first omitted item. Give no further assistance except (if necessary) to remind the participant to continue until instructed to stop.

### **Scoring**

- i) You should be seated where you can observe the participant closely. If the participant begins to work out of sequence after being redirected once, do not stop or redirect again. Make a note of the box and once the test is completed and the participant hands the worksheet to you, place an "X" in the box after the last correctly completed symbol (the symbol right before the second skipped box or start of working out of sequence again). Score only to that point.
- ii) Do not give credit for items that are drawn incorrectly or completed out of sequence (in a clustering or grouping fashion). Any boxes completed after the second "out of sequence" are not counted toward the total.
- iii) Use the Digit Symbol Scoring Template to check the participant's responses. Line up the template with the boxes on the participant worksheet. Note incorrect symbols by placing an X through them. Subtract the number of incorrect symbols from the number on the scoring template above the last symbol drawn to determine the total score.
- iv) Responses to the seven sample items are not included in the score.
- v) A response is scored as correct if it is clearly identifiable as the keyed symbol, even if it is drawn imperfectly or if it is a spontaneous correction of an incorrect symbol.
- vi) Record the score on the DSST form.
- vii) Maximum score = 133 points

## **15.5.8 Modified Rey-Osterreith Complex Figure**

**Description:** The Rey-O figure is a neuropsychological assessment in which examinees are asked to reproduce a complicated line drawing, first by copying and then from memory. The test is useful in the evaluation of different functions, such as visuospatial abilities, memory, attention, planning, and working memory (executive functions).

### **15.5.8.1 Specific Instructions for Administering the Rey-O**

This test has two parts:

Part A – Copy: Participant copies the figure

Part B – Immediate Recall: Participant draws the figure from memory

- Have the participant use a black pen.
- Laminated card with figure should be placed directly in front of the participant in correct landscape orientation ('kite' on right side and 'cross' on left side) with the blank piece of paper directly beneath it.
- Orient the participant response sheet landscape to match the laminated figure.
- Participant may not move or turn the drawing but s/he may move or turn the response sheet.
- Do not allow participant to draw on the figure.

### **Part A – Copy**

Examiner: ***"I would like you to make a copy of this drawing. Make sure that you look at the original carefully as you go along and try not to leave out any parts."***

- Give participant pen.
- Place the sheet entitled "Rey-O Copy" in front of the participant

There is no time limit for this test. If the drawing is careless, the participant should be encouraged to make the copy as accurate as possible.

### **Part B – Immediate Recall**

- Remove the drawing from view
- Place the sheet entitled "Rey-O Immediate Recall" in front of the participant

Examiner: ***"That was good. Next, I'd like to see how much of that drawing you can reproduce from memory. Even if you think you won't be able to remember very much, go ahead and try as best you can, even if it is just one single line that you remember.....Ready? Begin."***

Again, there is no time limit for this test; encourage the participant to do the best s/he can.

### **Scoring**

The Rey-O drawings will be scored centrally at the LIFE Cognition Coordinating Center and entered in to the LIFE database. Participant drawings should be either faxed or mailed to the CC.

### **15.5.9 Proxy Functional Assessment Questionnaire (FAQ)**

The FAQ is a brief, 10-item questionnaire that measures the impact of cognitive problems on important daily functions. The FAQ and cognitive tests are used to classify the cognitive status of all participants at baseline.

#### **15.5.9.1 Specific Instructions for Administering the FAQ**

At SV1 and 24 Month visits, if the participant scores  $\leq 88$  on the 3MSE, the FAQ must be administered ***within one month*** of the visit.

The FAQ is to be given to a proxy of the participant – someone who is in close contact with the participant and has knowledge about the participant's daily functioning. The proxy should be instructed to respond to each question based on the participant's ability during the past four (4) weeks.

The FAQ can be administered over the phone if permitted by local IRBs.

Say, ***"Hello. I'm \_\_\_\_\_ from \_\_\_\_\_ University/Clinic. I'm calling today on behalf of \_\_\_\_\_ (Ppt name) who has volunteered for the LIFE Study. He/She gave us permission to contact you if, during the study, we needed to collect some additional information about how their health might be affecting their ability to do certain things. This won't take more than 10 minutes and we really appreciate your willingness to do this.***

***I would like to ask you some questions about how Mr./Mrs. \_\_\_\_\_ handles some common daily functions. Using the following responses, please choose the most accurate representation of his/her level of ability to perform each activity in the past four weeks: (READ SLOWLY)***

***Normal***

***Has difficulty, but does by self***

***Requires assistance***

***Dependent***

***Not Applicable (e.g., never did)***

***In the past four weeks, did Mr./Ms. have any difficulty or need help with:***

Read each question and record the responses on the FAQ form. If needed, remind the contact that the time frame is within the past four weeks.

### **15.5.10 Telephone Interview for Cognitive Status (TICS; Brandt, 1988)**

**Description:** The TICS assesses global cognitive functioning similar to the 3MSE but can be administered over the phone. It assesses several cognitive abilities and can be completed in approximately 10 minutes. The TICS will be administered by telephone to those participants who do not complete a clinic or home visit.

#### **Materials Needed**

- Test Administration Form and Pen

#### **15.5.10.1 Specific Instructions for Administering the TICS**

- Use reasonable judgment in allowing sufficient time to answer a question.
- If a participant changes an incorrect response to a correct response at any time during the TICS, credit should be given for the correct response.
- Likewise, if the participant changes a correct response to an incorrect response, the new response should be recorded and credit should not be given.
- Participant responses should be recorded on the provided lines.
- Score each item. Sum these scores for the total score. Maximum score for the TICS is 51.

#### **Orientation to Name: Question 1**

- Participant should provide first and last name.
- 1 point for each correct first and last name.

#### **Orientation to Time and Place: Questions 2-7**

- Year:** Four or two digit year is acceptable.
- Seasons:** If near seasonal transitions, accept either season as correct. (e.g. late August – accept summer or fall, early March – accept winter or spring). Some regions have no clear seasonal change. May accept other common local references such as “dry season,” “rainy season,” etc.
- Month:** Participant should provide current month.
- Today’s date:** Participant should provide the current numerical date.
- Day of the week:** Participant should name specific day, i.e., Mon, Tues., etc.
- Age:** Participant should give his/her correct age.
- Address:** Participant should give his/her complete address including house number, street name, city, state, and zip code. If the participant resides in a nursing home or assisted living facility, s/he may not know the house number. If the name of the facility is provided, accept that for the house number and give 1 point. If s/he does not know the street name, no point is given for that question.
- Scoring:** 1 point for each correct response; 0 for incorrect response. Maximum for questions 1a – i = 9.

#### **Sustained Attention and Concentration: Question 8**

- Participant is asked to count backwards from 20 to 1.
- If participant did not correctly count backwards on Trial 1, then administer Trial 2.
- Score: 2 points if correctly completed Trial 1; 1 point if correctly completed Trial 2; 0 points if task not completed.

#### **Word Recall: Question 9**

- Slowly read the list of 10 words and ask the participant to recall as many of the words as possible.
- Mark each word the participant is able to recall

- iii) If the participant verbalizes that they did not hear or understand the word, you may repeat the word.
- iv) If the participant is misunderstanding a word you may accept the following substitutions:
  - Pipe: Hype, Type, Kite, Height, Pike
  - Silk: Quilt, Milk
  - Whip: With, Hip, Quip, Wit
  - Pillow: Willow, Hello, Jello, Yellow
- v) If you give credit for the substitution word the first recall, you cannot give credit for the correct word on the second recall. For example:
  - Participant says: Hype (correct), Pipe (incorrect)
- vi) Scoring:
  - 1 point for each correct response
  - No penalty for repetitions or intrusions, but do not count toward total
  - Plurals are considered correct
- vii) Maximum Score = 10

#### **Attention and Mental Calculation – Serial 7s: Question 10**

- i) Participant is asked to subtract 7 from 100 and continue subtracting until told to stop.
- ii) Do not coach the participant by saying “and 7 from \_\_\_\_ is?” Instead, provide a general prompt of “keep going”.
- iii) Write the participant’s response in the box below each number. Do not place check marks in the boxes.
- iv) Scoring:
  - Be careful when scoring this item. An answer is considered correct if it is **exactly 7 from previous answer**, regardless of whether that previous answer was correct.
  - 1 point for each correct subtraction (even if subtraction was from a previously incorrect response)
- v) Maximum Score = 5

#### **Naming: Questions 11-14**

- i) Q11: Shears or Scissors are the acceptable responses. Score = 1 point for correct response; 0 for incorrect response
- ii) Q12: A response of “12” = 1 point; 0 for any other response.
- iii) Q13: Score 1 point for “Cactus”; 0 for any other response.
- iv) Q14: Score 1 point for “Sheep” or “Lamb” only; 0 for any other response.

#### **Repetition: Questions 15-16**

- i) Question 15: ‘No ifs, ands or buts’ – articulate so all plural “s” endings are audible. Participant must repeat the phrase exactly as it is stated for 1 point.
- ii) Question 16: ‘Methodist Episcopal’
  - You may repeat the phrases if participant has difficulty BUT the score is based only on the first attempt to repeat the phrase.



### **Recent Memory: Questions 17-18**

- i) Participant must give both first and last name to receive 1 point.
- ii) Probe for the first name if only the last name is given.
- iii) Score 1 point for correct first and last name. 0 if not known.

### **Motor Speed and Dexterity: Question 19**

- i) Participant is asked to tap 5 times on the telephone receiver
- ii) Scoring = maximum of 2 points
  - 2 points if 5 taps are heard
  - 1 point if the participant taps more or less than 5 times
  - 0 points if no taps are heard

### **Opposites: Questions 20-21**

- i) **Q20** – ‘Opposite of west’
  - Score = 1 point for “East”; 0 points for any other response.
  - You may spell “west” if participant does not hear the word correctly (hears wet and responds with dry).
- ii) **Q21** – ‘Opposite of generous’
  - Acceptable responses – selfish, greedy, stingy, tight, cheap, mean, meager, skimpy or other good antonym
  - Score = 1 point for a correct response; 0 otherwise

### **Short Term Memory: Question 22**

- i) Participant is asked to recall as many of the words as possible from the list of 10 words previously read.
- ii) Place a check for each word the participant is able to recall.
- iii) Scoring:
  - 1 point for each correct response
  - No penalty for repetitions or intrusions
  - Plurals are considered correct
- iv) Maximum Score = 10

#### **15.5.11 Dementia Questionnaire (DQ)**

**Description:** The DQ is a questionnaire administered to a proxy/informant, by phone, to assess cognitive and behavioral changes and to determine how cognitive problems affect everyday functions. The DQ will be administered to proxies of those participants who cannot be assessed in person (refused clinic or home visit) or scored <30 on the TICS. For participants that have died, the DQ will be obtained with other study outcome forms.

##### **15.5.11.1 Specific Instructions for Administering the DQ**

- i) Contact the proxy as soon as possible. It is important to inform the proxy that this type of interview is standard procedure in memory studies and that the participant has given permission for it. Refusals by the friend/family member are handled in these ways:

- a. Request that the friend or family member speak with the participant to assure them that the participant indeed granted permission for the interview.
  - b. OR, request that the study participant contact their friend or family member to confirm that permission has been given for the interview.
- ii) If the participant died within 6 months after randomization, you do not need to get the DQ.
- iii) Conduct the interviews without interruptions, if possible. It may be necessary to make a preliminary call to the designated individual and schedule a time for the interview. **If possible, you should not conduct the interview if the study participant is present.**
- iv) Make sure you have the contact information and interview forms prior to making your call.
- v) If the site staff are unsuccessful in contacting the proxy after four (4) call attempts, a letter will be sent to the proxy stating they have been trying to reach them.
- vi) For each question asked, check only one box from the following choice of answers:  
Yes/No – (Self-explanatory)  
DK/NR – Don't know OR No Response
- vii) For questions requiring a 'Year' response, 'year' relates to the approximate year of onset. If the friend/family member does not know the year, code as "8888"; however, try to elicit a response.

Say, **Hello Mr/Mrs \_\_\_\_\_, my name is \_\_\_\_\_ and I'm calling from the LIFE Study at (site name). Mr/Mrs \_\_\_\_\_ is a participant in the study and he/she receives assessments of his/her cognitive functioning. S/He has given us permission to speak with you about him/her. I would like to ask you a series of questions about (participant's name) memory and other cognitive abilities. By answering these questions, we will get a better idea about his/her cognitive ability and health status. The interview will take approximately 20 minutes. Is this a good time for us to talk?**

### **Informative: Questions 1-3**

These questions are designed to be informative and to determine if the proxy/informant seems reliable.

1. **How long have you know him/her?**
2. **How often did/do you have contact with him/her?**
3. **Most frequent type of contact?**

### **I. Memory/Cognition: Questions 4-13**

Ask all questions. If YES, obtain year of onset.

4. **Did (if deceased)/Does Mr/Mrs \_\_\_\_\_ have any problems with memory?**
5. **Did/Does Mr/Mrs \_\_\_\_\_ have trouble remembering people's names?**
6. **Did/Does Mr/Mrs \_\_\_\_\_ have trouble recognizing familiar faces?**

- 7. How about finding his/her way around indoors. Did/Does he/she have trouble with this?**
- 8. Did/Does he/she have trouble finding his/her way around familiar streets?** (Tip: Ensure that the friend/family member answers according to what is familiar to the participant.)
- 9. Did/Does Mr/Mrs \_\_\_\_\_ have trouble remember a short list of items?** (grocery list, to do list, etc.)
- 10. Did/Does Mr/Mrs \_\_\_\_\_ have trouble finding the right word or expressing him/herself?**
- 11. Did/Does he/she have trouble grasping situations or explanations?**
- 12. Did/Has his/her talking become less over time?**
- 13. Did/Does he/she have a tendency to dwell in the past?**

If NO to all, go to Question 22.

## **II. Onset and Course: Questions 14-19**

Ask questions in this section **ONLY** if the subject has/had cognitive problems (i.e., responded YES to any Question 4-13). Otherwise, skip to Section IV.

Say, “**You mentioned Mr/Mrs \_\_\_\_\_ has/had problems with \_\_\_\_\_**” (refer to Questions 4-13)

- 14. Did these problems begin suddenly or slowly?** (choose only one answer)
- 15. Have these problems stayed the same, been steadily getting worse, or have there been abrupt declines?** (choose only one answer) Make any necessary notes explaining your answer.
- 16. Is a doctor aware of these problems?** (If YES, go to Question 17. If NO or DK/NR, go to section III)
- 17. What does the doctor believe is causing the problems?** (choose only one answer)
- 18. Name and address of first doctor seen for memory problems.**
- 19. Did he/she receive medications for memory problems?**

## **III. Recognition of Problem: Questions 20-21**

Ask questions in this section **ONLY** if subject has cognitive problems (i.e., responded YES to any Question 4-13). Otherwise, skip to Section IV.

- 20. What was first noticed (the first 3 symptoms noticed)?** (Obtain year of onset)
- 21. When was the last time he/she seemed to be really well or his/her old self?** (Obtain year)

## **IV. Caregiving: Questions 22-25**

Ask as open ended question, interviewer puts the story together. If YES and DK/NR year, mark 8888. If DK/NR, mark year 9999.

**22. Is an in-home paid caregiver ever utilized (full or part-time)?** (If YES, obtain year and go to Question 22a. If NO, go to Question 23. If DK/NR, obtain year and go to Question 23.)

**22a. How long was the caregiver utilized (in months)?**

**22b. Why was the caregiver utilized?**

**23. Did he/she ever move in with relatives?** (If YES, obtain year and go to Question 23a. If NO, go to Question 24. If DK/NR, obtain year and go to Question 24.)

**23a. How long did he/she live with relatives (in months)?**

**23b. Why did he/she move in with relatives?**

**24. Did he/she ever reside in assisted living and/or board & care home?** (If YES, obtain year and go to Question 24a. If NO, go to Question 25. If DK/NR, obtain year and go to Question 25.)

**24a. How long did he/she reside in assisted living/board & care (in months)?**

**24b. Why did he/she move to assisted living and/or board & care home?**

**25. Did he/she ever reside in a nursing home?** (If YES, obtain year and go to Question 25a. If NO, go to Question 26. If DK/NR, obtain year and go to Question 26.)

**25a. How long did he/she reside in a nursing home (in months)?**

**25b. Why did he/she move to a nursing home?** (mark most prominent)

#### **V. Daily Functioning: Questions 26-33**

Use the following interpretation for the codes:

0=no problems or never did but could

1=independent but more difficult or problems noticed

2=need prompting, supervision, assistance, or dependent

**26. Did/Does he/she ever have trouble with household tasks: using microwave, light cleaning (i.e., putting items away)?**

**27. Did/Does he/she ever have trouble with handling money: paying bills, making change, writing checks, balancing check book, taxes, investments?**

**28. Did/Does he/she ever have trouble dressing: choosing or changing clothes, tying shoes, using fasteners?**

**29. Did/Does he/she ever have trouble feeding self: using cups or utensils, cutting meat, buttering bread?**

**30. Did/Does he/she ever have trouble bathing: knowing what to do in the shower or tub, knowing how to wash?**

**31. Did/Does he/she ever have trouble controlling bladder or bowels?**

**32. Did/Does he/she ever have trouble remembering to take medications?**

**33. Did/Does he/she ever drive?** (If YES, go to Question 33a. If NO or DK/NR, go to Question 34.)

**33a. Did he/she ever stop driving?** (If YES, obtain year and go to Question 33b. If NO, go to Question 33c)

**33b. Why did he/she stop driving?**

- 33c. Is/did he/she having/have any problems?**  
**33d. What type of problems?**

**VI. Medical Problems: Questions 34-47**

- 34. Did/Does he/she ever have high blood pressure?**  
**35. Did he/she ever have a stroke?** (Symptoms unresolved or >24 hours) (If YES, obtain year of onset)  
**36. Did he/she ever have a TIA?** (Symptoms resolved ≤24 hours) (If YES, obtain year of onset)  
**37. Is one side of the body weaker than the other side?** (If YES, obtain year of onset and ask Why?)  
**38. Did/Does he/she ever have Parkinson's disease (resting, tremor, shuffling gait, limb rigidity)?** (If YES, obtain year of onset)  
**39. Did/Does he/she ever have epileptic seizures or fits?** (If YES, obtain year of onset)  
**40. Did/Does he/she ever have a drinking problem?** (If YES, go to Question 40a. If NO or DK/NR, go to Question 41)  
    **40a. Does he/she have memory/thinking problems that could be due to drinking?**  
**41. Was/Has he/she ever been depressed or sad for two or more weeks?** (If YES, obtain year and go to Question 41a. If NO or DK/NR, go to Question 42)  
    **41a. Did he/she ever seek treatment?**  
**42. Did/Does he/she ever have hallucinations (see things there)?** (If YES, obtain year of onset)  
**43. Did/Does he/she ever have delusions (false beliefs, people stealing, wanting to harm, cheating)?** (If YES, obtain year of onset)  
**44. Did/Does he/she ever have agitation and nervousness?** (If YES, obtain year of onset)  
**45. Did he/she ever seek psychiatric help for any reason?** (If YES, go to Question 45a. If NO or DK/NR, go to Question 46)  
    **45a. Has he/she ever been hospitalized for psychiatric illness?** (If YES, obtain year and location)  
**46. Did he/she ever have a neurological or psychiatric exam?** (If YES, enter date, location, reason)  
**47. Did he/she ever have a CT scan or MRI of the head?** (If YES, enter date, location, reason)  
Ask about any additional medical conditions not yet discussed. If YES to any Question 45-47, mention to informant that we may want to obtain medical records, then fax a medical records request.

Say, "Those are all the questions I have for you Mr/Mrs \_\_\_\_\_. On behalf of the LIFE Study, I would like to extend our appreciation to you for taking time to speak with me."

### **15.5.12 E-Prime Computerized Tests**

#### **Materials Needed:**

- Laptop computer
- Laptop power cable
- Computer files for tests:
  - a) 1\_flanker.ebs2,
  - b) 2\_oneback.ebs2
  - c) 3\_twoback.ebs2
  - d) 4\_taskswitching.ebs2
- Laminated examples for use with each test
- Laminated place cards indicating what the Z and M keys represent for each test
- Dry erase pen for writing on laminated examples
- Computer keyboard overlay
- Computerized Cognitive Tests Checklist Form
- Digital recorder and batteries

#### **15.5.12.1 Start-Up Procedures**

- i) Before the participant arrives for testing (in order to minimize participant wait time), the laptop should be plugged in and started (do not operate from the battery if at all possible). The computer should always be started from a complete shutdown. If the computer was not completely shut down after the previous day's testing and was left on standby or hibernate, there is a chance it will crash during the current session.
- ii) When ready to begin testing, double click on the first test's icon (1\_flanker) located on the desktop. Begin recording the session at this time.
- iii) Enter participant ID and visit number (NOTE: 1=Screening Visit 2, 18=18 month Visit, and 30=30 month Visit, clicking "OK" after each entry. (NOTE: You should only have to enter this information one time [when you begin the flanker test]. Each test that follows will recognize the current participant's information and write the data files accordingly.)
- iv) A window summarizing the participant information you just entered will now appear on the screen with the header "Summary of Start-up Info." Verify this information, then click "Yes" to continue on to the testing. (NOTE: If you made a mistake entering the participant information, click "No," and you will be taken back to the participant ID entry screen to re-enter all participant information again. If you need to escape the task altogether, press "Cancel" to exit).
- v) You will now see a screen that says "Verifying Participant ID..." If you have entered a valid ID, then the first screen of instructions for the flanker task will soon appear. If you have NOT entered a valid ID, you will see a message stating "Invalid participant ID. Exit and restart the test" and an "OK" box. At this point, you should press the Enter key, which will return you to the desktop. Double click on the 1\_flanker icon to start again.

#### **15.5.12.2 Troubleshooting Tips for E-Prime Computer Programs**

**Responding to the message “Do you want to overwrite?” when entering participant number and test session:**

Responding “Yes” to this question will overwrite data from a previous test session that has the same participant identifying information as the one you are currently entering.

If you get this message in error and are not attempting to replace a participant’s previous session, answer “No” to this question and review the participant information carefully to make sure that there were no mistakes in the entry.

**To pause during a test:**

Press **CONTROL** and **SHIFT** simultaneously. This applies only to the 1-back and 2-back tasks where the stimuli move forward regardless of whether the participant has responded with a key press. Because the flanker and task-switching tests only advance when a participant makes a key press, you can pause at any time without special action.

**To discontinue any test at any time (almost never do this):** Only stop a task if your participant refuses to continue despite your best efforts at encouragement (the consent form states that a participant can stop participation at any time), becomes so distressed that it is impossible for him/her to continue, or you think s/he will quit the testing session entirely. To stop the task, press ALT, CONTROL and SHIFT simultaneously.

**Interrupting testing to repeat instructions:**

Interrupting the testing at any time should be done judiciously as it can harm standardization. However, you may find you need to do so in order to clarify the instructions or if the participant expresses confusion/distress. These are good reasons for an interruption.

If you do need to interrupt a participant, ONLY TWO interruptions per test (maximum of 8 interruptions in total across the entire battery) is allowed during the actual testing. If the participant is still struggling with understanding the task after you have stopped twice on a given test, tell the participant to continue on and just do his/her best. Please note more specific instructions for task interruption are given below for each task.

Also, make sure you note any interruption and the reason for it on the Computerized Cognitive Tests Checklist form (e.g., mixed up z and m keys).

**Computer software/hardware malfunction:**

In the RARE event that the computer freezes or shuts down during a test, reboot the laptop and begin the test again.

- i) You should not have to re-enter any participant information unless you were interrupted before completing the flanker task. Return the

- participant to the beginning of the test that was interrupted and repeat the instructions.
- ii) If the participant completed the practice session for a given test before the computer froze/crash, do not repeat the practice session. Advance through the practice trials yourself and then have the participant re-start the test at the beginning of the interrupted test.
  - iii) Also be sure to note on the Computerized Cognitive Testing Checklist form that the computer malfunctioned, on which task this occurred, and indicate that the test was re-started.

**Computerized Cognitive Testing Checklist Use:** Write down anything that occurs during a session that may have had an effect on a participant's task performance under Question 2 of the E-Prime checklist. No detail is too small or unimportant to be noted.

### **15.5.12.3 Specific Instructions for Administering the E-Prime Test Battery**

Introducing the Test Battery at Screening Visit 2:

***Examiner: "Today, we're going to do a series of tasks that will challenge your memory and other thinking abilities, and we'll be using a computer. I will explain the instructions before you start each test. Regardless of your experience with computers, you will be able to do these tests. Each one has a practice session to allow you to get comfortable and understand exactly what is being asked of you. Please feel free to let me know if you have any questions along the way or if anything is unclear. I want to remind you that that I will be tape-recording our session today. Do you have any questions?"***

Introducing the Test Battery at the 18 Month or 30 Month Visit:

***Examiner: "Today, we're going to do a series of tasks that you have done before. These tasks are the ones that involve the computer. You may have found some of these tasks to be difficult when you did them the first time as some of them have been designed to be demanding and push the limits of what you are able to do. Please remember that these tasks are difficult for everybody and all we ask is that you try your best. This is the last time that you will do these computer tasks. However, they are very important to our study so we ask you to please try to complete all of the tasks to the best of your ability.***

***Just like the first time you did these tasks, I will explain the instructions before you start each task. Regardless of your experience with computers, you will be able to use the computer to perform these tasks. Each one has a practice session to allow you to get familiar with the task and help you understand what is being asked of you. Please feel free to let me know if you have any questions along the way or if***



***anything is unclear. I want to remind you that that I will be tape-recording our session today. Do you have any questions?"***

**What to do if a participant needs additional coaxing to perform the Test Battery during their follow-up visit:**

Given some participants have expressed concern/distaste for performing the computer battery again, you might find that additional coaxing or reassurance is needed to motivate them. If this is the case, do your best to get them started on the battery saying things like ***"Well, let's just try the first task and see how it goes"*** and ***"You may remember that the first task is not too bad. It is the one where you simply have to look at arrows on the computer screen and indicate whether the arrow points to the left or the right. So, why don't we give that task a try and then see how you feel about doing the others."***

It should not be too difficult to get your participants through the flanker task but they may already be anticipating the 2-back task, which is the most demanding. If that is the case, try to encourage them to just think one task at a time by saying things like ***"I know some of the tasks that come later in the session are difficult but let's just focus on one task at a time. Remember the first couple of tasks we do are fairly straightforward, so let's just concentrate on those for now"***.

Participants do not seem to have minded the flanker task or even 1-back too much, so you should be able to coax them through those two tasks without too much trouble. The task that is no doubt the most problematic is the 2-back task. Please follow the advice given below in the 2-back test section regarding how to help your participants get through the 2-back task once they have begun it. As for introducing the 2-back test, once you have given the following instructions ***"This task is similar to the one you have just completed. However, there is ONE important difference...displayed TWO letters back, not immediately before like the last task"***, you may hear a groan or two from your participants. If that is the case, then at this point try to encourage them by reiterating the following points from when you introduced the battery by saying things such as, ***"I know that this task is difficult. It is difficult for everybody and is meant to really push you. In doing so it provides us with very useful information for this study, and all we ask is that you try your best. This is the last time that you will have to carry out this task. Also in our experience, people perform better on this task than they think they do, so please try to keep that in mind if you become frustrated."***

If the participant continues to be distressed or concerned, remind them that this is a task that is demanding for everyone but is very important for the study, and encourage them to do the best they can to continue with the task, making their "best guess" as to the correct response for each item

Following 2-back, it should not be too difficult to have participants complete the final measure (task switching). If necessary, remind them that this is the last task of the computer session and they will soon be finished.

**Administering Task Instructions:** Apparently some subjects have been a little “trigger happy” during the instruction phase of the tasks, and have been pressing the “m” or “z” key to advance the instruction screens before you are ready to have them go to the next screen. It is fine to remind your participants each time the first instruction screen of a task appears on the monitor to ***“Please do not press any keys until I tell you to do so”***, and to insist on that somewhat more strongly if they ignore you by gently touching their wrist and reminding them again.

#### 15.5.12.3.1 **Flanker Test**

**Test Description:** Participants are presented with a target arrow facing either right or left and asked to press a computer key indicating its direction. The target arrow is flanked by two arrows on the right and two arrows on the left. The arrow displays can be congruent (flanker arrows point in the same direction as the target arrow) or incongruent (the flanker arrows point in the opposite direction). The test begins with one practice block of 8 trials.

**Setup:** Place the Flanker test laminated place card above the keyboard to remind participant that **M = right** and **Z = left**. **Have the laminated illustration of a group of arrows on hand to show the participant what the stimuli will look like, as well as a dry erase pen to emphasize the location of the central arrow.**

**Monitoring Participant Performance:** While the participant is completing this test, observe the responses and make sure that the participant is following instructions. Look for errors or problems, such as:

- ii) Key Pressing issues. Mixing up the M and Z keys, pressing the same key repeatedly (Solution: pause the test and explain again that they need to use Z to indicate left and M to indicate right), inadvertently resting (and thus pressing) fingers on the M and/or Z key. Response Speed Issues. Make sure that the participant is trying to perform the test as quickly and accurately as possible. If you notice that a participant’s responses are especially slow, remind him/her that it is important to ***“respond as quickly and accurately as possible.”*** Unfortunately, in making the decision as to whether you should remind your participant that speed is important for the task, you will need to rely on your own judgment as to whether the participant is simply a slow responder across all tasks and is, in fact, going as fast as possible or if the participant has settled on a speed/accuracy tradeoff for the flanker task that favors accuracy over speed. If the participant

has tended to be “slow-moving” throughout the session prior to the administration of the eprime tasks, then reminding them to respond as quickly and accurately as possible may hurt their performance and so should be avoided. If instead their slow performance seems to be specific to the flanker task, then reminding them about speed and accuracy is the correct thing to do.

- iii) Need for a Task Interruption. Remember—DO NOT stop the participant more than twice during the actual test to make corrections or clarification.

**Test Timing:** This test is self-paced and will only advance when a participant makes a key press response. It takes approximately 5 minutes to complete.

**Instruction on Flanker Test Procedure and Screen Order:** As described above, the flanker test will start once you have double-clicked on the flanker icon (1\_flanker) located on the desktop. If you have not already done so, follow the instructions given above under “Start-Up Procedures” (15.5.12.1).

- i) The first page that appears for the flanker test will contain the following instructions (in italics) which you will read out loud to the participant. Please show the laminated examples while you read at the times indicated by the boxes in the text:

Examiner: ***“In the following test, we’d like you to indicate whether the center arrow in a set of 5 arrows points left or right.”***

Here, show an example grouping of arrows (on the laminated example page) and indicate the location of the central arrow, circling it with the dry erase pen for further emphasis.

Examiner: ***“If the arrow points left, press the Z key with your left index finger as fast as you can. If it points right, press the M key with your right index finger as fast as you can while remaining accurate.”***

Examiner: ***“The other arrows may face the same or opposite direction, but ignore them and make your response based on the center arrow.”***

Examiner: ***“Position your index fingers on the Z and M keys, and then press the M key for more instructions.”***

- ii) Read through these instructions aloud with the participant. Help them place their left index finger on the Z key and their right index finger on the M key. (Remember to place reminder card showing that Z=left and M=right on the laptop at this point if you haven’t already.) Have the participant press M to move on to the second page of instructions.

- iii) The next page reiterates that they only need to concentrate on what direction the center arrow is pointing and quickly indicate this direction by pressing the appropriate key. It also illustrates what a left center arrow and a right center arrow will look like in the test. Please read these instructions to the participant as they appear on the screen, and then ask the participant if s/he has any questions before beginning the practice trials.

Examiners: ***“Remember, press the Z key if the center arrow points left, and the M Key if the center arrow points right.***

***< = left***

***> = right***

***Respond as fast as you can while remaining accurate.  
Press the Z key to start some practice trials.”***

- iv) This test includes only one practice block containing eight trials—see box below if an additional practice is needed. Watch the participant’s responses to ensure that the test is understood but do not stop the practice block unless the participant expresses confusion or distress.
- v) At the end of the practice, a new screen will appear with instructions to be read below. At this point, ask the participant to reiterate for you what they are supposed to do:

Examiner: ***“Now that we’ve gone through the instructions and you’ve had a chance to practice the test, why don’t you tell me in your own words what you are supposed to do so I know I’ve made everything clear.”*** If satisfactory, read the final screen instructions:

Examiner: ***“Please ask if you have any questions.”***

Examiner: ***“When you are ready, you may go ahead and start the actual test.”***

Examiner: ***“Press the ‘M’ key to begin.”***

- vi) When you and the participant are ready, have the participant press the M key as instructed to move on.

**If the participant requests additional practice:** Use the laminated example page to make sure they understand the task. Cover all but the first series of arrows on the page with another piece of paper and move down each series asking the participant what his/her response is for each one. Only one additional review of the instructions is allowed.

- vii) The actual Flanker test consists of 80 sets of arrows (e.g., 80 trials).

- viii) At the end of the last trial, a screen will appear prompting the participant to ask for additional instruction from you. This screen will automatically disappear after a few seconds, and you will be taken back to the desktop.
- ix) **If any problems occurred during the Flanker test please note them on the Computerized Cognitive Tests Checklist Form.**

#### **15.5.12.3.2. The One-back Test**

**Test Description:** Individual letters are presented one at a time at a 2-second rate on the computer screen and participants are asked to indicate whether the presented letter is the same as the letter that appeared immediately before it in the sequence. Letters may be presented in upper or lower case (capital or small letter) form and participants must make their response based on the letter's name (not its case).

For example, participants might see "m, a, A" and they would respond DIFFERENT to "a" and SAME to "A". No response should be made for the first letter that appears (since there is no previous letter to compare it to). The program will automatically choose whether one, two or three practice blocks are included based on the participants' performance. Criterion for passing a practice block is getting 6 or more items correct.

**Setup:** Place N-back laminated place card above the keyboard to remind the participant that M = same and Z = different. **Have the laminated example page nearby, along with a dry erase pen.**

**Monitoring Participant's Performance:** As with the prior Flanker Test, be attentive to the participant's responses during the test. Watch to make sure there are no problems, such as:

- i) Key pressing issues. Mixing up the Z and M keys, just pressing one key repeatedly, or neglecting to press any keys at all (Solution: pause the test [CTRL+SHIFT] and explain again that they need to use M to indicate same **and** Z to indicate different), and inadvertently resting (and thus pressing) fingers on the M and/or Z key. You will have to watch the participant's fingers carefully to catch one of these mistakes because the test will continue to advance even if the participant is not pressing the keys properly.
- ii) A Need to Interrupt the Task. If the participant voices or expresses confusion (even in his/her task performance) or distress in any manner, including being overwhelmed because the "task is moving too quickly" and needs a minute to re-group, pause the task. Also be sure to pause the task if you are going to speak to your participant at any time while the task is running so the participant's attention is not divided between listening to you and working on the task. To pause the task, you should ask the subject to excuse you as you reach over the keyboard to press CTRL + SHIFT. It will be faster if you

pause the task yourself than if you request the participant do so. Once the task is paused, encourage your subject to take a minute to compose him/herself and ensure that s/he understands the instructions by asking him/her to first tell you again in their own words what the task requires. If your participant is unable to do this, you can remind them of the instructions (read from the MOP and use the laminates to do so, do NOT restart the task).

You may reiterate the instructions only once using the laminated example if necessary. You cannot stop the testing more than twice for any reason once the participant has started the actual test. When your participant is ready to recommence the task, tell him/her that when the task begins to ***“Restart the test as if the next letter that appears is the FIRST letter of the test—do not worry about remembering the letter that appeared before you paused”***. Pressing the SPACEBAR will restart the task.

**Test Timing:** The test takes approximately 7 minutes to complete from the beginning of the instructions to the end of the test, depending on whether the participant completes 1, 2, or 3 practice blocks. This test is computer-paced (i.e., the test will advance even if the participant has not given a response for a trial) and you can use the pause function (CTRL+SHIFT) if needed.

In the event that the testing is paused, prompt the participant as follows:  
***“Restart the test as if the next letter that appears is the FIRST letter of the test—do not worry about remembering the letter that appeared before you paused.”***

**Special Instructions re. Task Pacing:** Before beginning this test, it is IMPORTANT that you:

- i) Let the participant know that this test moves at a fairly quick pace and will advance if enough time passes regardless of whether or not a response has been made. Explain that this might make it difficult, but that s/he should just do his/her best.
- ii) Tell the participant that if s/he gets “lost”, s/he should simply pick up the sequence again starting with the current letter seen on the screen (***“Restart the test as if the next letter that appears is the FIRST letter of the test—do not worry about remembering the letter that appeared before you paused”***).
- iii) Be conscious that each letter appears on the screen for 2000 msecs (2 secs) and the participant must respond during that interval. Once the letter goes off the screen the response is no longer recorded. If a participant is slow to respond, remind him/her to respond as quickly and accurately as possible so that the computer will record the answers properly.

**Instructions and Screen Order for Running the “1-Back test”:** Begin the “One-back test” by double-clicking on its icon (2\_oneback) located on the desktop. The first page that appears will contain the following instructions which you will read to the participant:

Examiner: ***“In this task, you will see letters appear one at a time. For each letter, I would like you to indicate whether it’s the same as or different from the letter that came immediately before it.”***

Examiner: ***“These letters may be presented in upper and lower case form. Do not pay attention to the visual appearance of the letter, simply decide if the letter on the screen matches the one that came immediately before.”***

Examiner: ***“For this task it is important to remember that you are going to be making a response after the presentation of EVERY letter (except the first one). After each letter appears, you are to compare it to the one shown immediately before the current letter.”***

- i) After reading through those instructions with the participant, use the examples below the instructions to practice. Use the blank side of the laminated example page to cover the rest of the examples on the screen so that the participant only sees one at a time, and ask the participant:

Examiner: ***“For example, if the letter ‘J’ appeared, what would your response be?”***

(NOTE: make sure participant responds by saying either “**same**” or “**different**” and not “yes” or “no”). The letters on the screen and their correct responses are: J - “none”, N – “different”, n – “same”, s – “different”, s – “same”, P – “different”. Keep in mind that the correct responses are not displayed on the computer screen so you will need to know them.

- ii) Always remind participants that although on this example they can easily look back in the list to see what letter came one back, during the actual test they will only be seeing one letter at a time (i.e. they will have to rely on their memory to recall the one-back letter).
- iii) After working through these examples, have the participant press M to continue to the next screen of instructions.
- iv) The second page will contain the following instructions. Please note the use of the laminated example in the box below.

As you are reading through the instructions point to the laminated example page to reinforce the test requirements. It may help to draw

arrows on the laminated example page from the current letter to the letter the participant is going to be comparing.

Instruct the participant as follows:

Examiner: ***“As you just saw, your task is to keep track of the letters and once the 2<sup>nd</sup> letter has appeared, indicate whether it’s the same as or different from the 1<sup>st</sup> letter. When the 3<sup>rd</sup> letter appears, indicate whether it’s the same as or different from the 2<sup>nd</sup> letter and so on.”***

Examiner: ***“You will indicate ‘SAME’ by pressing the ‘M’ key, and ‘DIFFERENT’ by pressing the ‘Z’ key.”***

Examiner: ***“Press the ‘M’ key for more instructions.”***

- v) After the participant has pressed the ‘M’ key to continue on, the third page will contain the following instructions regarding the practice trials:

Examiner: ***“Now let’s try some practice trials.”***

Examiner: ***“Remember, you will indicate ‘SAME’ by pressing the ‘M’ key, and ‘DIFFERENT’ by pressing the ‘Z’ key.”***

Examiner: ***“Again, make a response after EVERY letter except for the first one.”***

- vi) Remember to inform participants that the task will move quickly ***“The letters will only be on the screen for a few seconds, so it’s important to make your response as quickly as possible.”*** Note that this instruction is not presented on the computer screen.

Examiner: ***“To start the practice trials, press the ‘M’ key.”*** Have the participant press M to continue on to the first practice block.

- vii) The practice trials that follow will consist of 10 letters.
- viii) Watch the participant’s responses to ensure that the task is understood but do not stop the practice block unless the participant expresses confusion or distress.
- ix) If the participant met the criterion for passing (6 or more correct items), the program will advance to the actual test, and you can move on to the directions below.
- x) If the participant did not meet the criterion for passing, the program will move to a second practice block, and then a third practice block if the criterion was still not met. Follow these directions if a second practice block and/or third practice block is needed:
  - (1) Have the participant press the spacebar when s/he is ready to continue to the second practice block if the criterion was not met



during the first practice block. The second practice block also contains 10 letters.

- (2) Have the participant press the spacebar when s/he is ready to continue on to the third and final practice block (also 10 letters) if s/he did not meet criterion during the second practice block.
- xi) At the end of the last practice block (1st, 2nd, or 3rd), a new screen will appear with the instructions to be read below. ). At this point, ask the participant to reiterate for you what they are supposed to do:

Examiner: ***“Now that we’ve gone through the instructions and you’ve had a chance to practice the test, why don’t you tell me in your own words what you are supposed to do so I know I’ve made everything clear.”*** If satisfactory, read the final screen instructions.

Examiner: ***“In this test, the computer will advance even if you have not made a response, so please work as quickly as you can.”***

Examiner: ***“Please ask if you have any questions.”***

Examiner: ***“When you are ready to start the actual test, press the ‘M’ key.”***

- xii) The 1-Back test consists of 46 letters, 45 of which the participant will respond to (no response for the first letter that appears). At the end of the last trial, you will see “That’s all for this part,” and then the program will automatically exit to the desktop.
- xiii) **If any problems occurred during the 1-back test please note them on the Computerized Cognitive Tests Checklist Form.**

#### **15.5.12.3.3 The Two-back Test**

**Task Description:** Individual letters are presented one at a time at a 2-second rate on the computer screen and participants are asked to indicate whether the presented letter is the same as the letter that was presented two items earlier in the sequence. Letters may be presented in upper or lower case form, but the participant should make their response based on the letter’s name (not its case).

For example, participants might see “m, a, d, A” and they would respond DIFFERENT to “d” and SAME to “A”. No response should be made for the first two letters that appear (since there are not previous letters with which to compare). The program will automatically choose whether one, two or three practice blocks are included based on the participant’s performance. Criterion for passing a practice block is getting 5 or more items correct.

**Setup:** Place N-back laminated place card above the keyboard to remind the participant that M = same and Z = different. **Have the laminated example page nearby, along with a dry erase pen.**

**Monitoring Participants' Performance:** As with the prior test, the “One-Back” Test, be attentive to the participant’s responses during the test. Watch to make sure there are no problems, such as:

- i) Key pressing issues. Mixing up the Z and M keys, just pressing one key repeatedly, or neglecting to press any keys at all (Solution: pause the test (CTRL+SHIFT) and explain again that they need to use M to indicate same **and** Z to indicate different), and inadvertently resting (and thus pressing) fingers on the M and/or Z key. You will have to watch the participant’s fingers carefully to catch one of these mistakes because the test will continue to advance even if the participant is not pressing the keys properly. .
- ii) 1-back responses by mistake. Giving responses that would have been appropriate for 1-back but are not correct for 2-back (Solution: pause the test [CTRL+SHIFT] and explain the task instructions again).
- iii) A Need to Interrupt the Task. If the participant voices or expresses confusion (even in his/her task performance) or distress in any manner, including being overwhelmed because the “task is moving too quickly” and needs a minute to re-group, pause the task. Also be sure to pause the task if you are going to speak to your participant at any time while the task is running so the participant’s attention is not divided between listening to you and working on the task.

To pause the task, you should ask the subject to excuse you as you reach over the keyboard to press CTRL + SHIFT. It will be faster if you pause the task yourself than if you request the participant do so. Once the task is paused, encourage your subject to take a minute to compose him/herself and ensure that s/he understands the instructions by asking him/her to first tell you again in their own words what the task requires. If your participant is unable to do this, you can remind them of the instructions (read from the MOP and use the laminates to do so, do NOT restart the task).

You may reiterate the instructions only once using the laminated example if necessary. You cannot stop the testing more than twice for any reason once the participant has started the actual test. When your participant is ready to recommence the task, tell him/her that when the task begins to ***“Restart the test as if the next letter that appears is the FIRST letter of the test—do not worry about remembering the letter that appeared before you paused”***. Pressing the SPACEBAR will restart the task.

**Test Timing:** The test takes approximately 7 minutes to complete from the beginning of the instructions to the end of the test depending on whether the participant completes 1, 2, or 3 practice blocks. This test is computer-paced (i.e., the test will advance even if the participant has not given a response for a trial) and you can use the pause function (CTRL+SHIFT) if needed.

In the event that the testing is paused, prompt the participant as follows:

***“Restart the test as if the next letter that appears is the FIRST letter of the test—do not worry about remembering the letter that appeared before you paused.”***

**Special Instructions re. Task Pacing:** Before beginning this test, it is IMPORTANT that you:

- i) Let the participant know that this test moves at a fairly quick pace and will advance if enough time passes regardless of whether or not a response has been made. Explain that this might make it difficult, but that s/he should just do his/her best.
- ii) Tell the participant that if s/he gets “lost”, s/he should simply pick up the sequence again starting with the current letter seen on the screen (***“Restart the test as if the next letter that appears is the FIRST letter of the test—do not worry about remembering the letter that appeared before you paused”***).
- iii) Be conscious that each letter appears on the screen for 2000 msecs (2 secs) and the participant must respond during that interval. Once the letter goes off the screen the response is no longer recorded. If a participant is slow to respond, remind him/her to respond as quickly and accurately as possible so that the computer will record the answers properly.

**Instructions and Screen Order for Running the “2-Back Test”:** Begin the “Two-back test” by double-clicking on its icon (3\_twoback) located on the desktop. The first screen that appears will contain the following instructions which you will read to the participant:

Examiner: ***“This task is similar to the one you have just completed. However, there is ONE important difference. You will still be responding after the presentation of every letter, but this time you are going to be comparing the present letter with the one displayed TWO letters back, not immediately before like the last task.”***

Examiner: ***“So for this task, you will again see letters appear one at a time. For each letter, please indicate whether it’s the same as or different from the letter that occurred TWO letters before it.”***

Examiner: ***“Press the ‘M’ key for more instructions.”*** Once the participant has pressed the ‘M’ key, the second page will contain the following instructions to be read:

Examiner: ***“Again, like last time, letters may be presented in upper and lower case form. Do not pay attention to the visual appearance of the letter, simply decide if the letter on the screen matches the one that came TWO letters before.”***

Examiner: ***“For this task it is important to remember that you are going to be making a response after the presentation of EVERY letter (except the first two). After each letter appears, you are to compare it to the one shown two letters before the current letter.”***

After reading through these instructions, use the examples below the instructions to quiz the participant as you did for 1-back, revealing one example to the participant at a time. Use the blank side of the laminated example page to cover the rest of the examples on the screen so that the participant only sees one at a time, and ask the participant:

Examiner: ***“For example, if the letter ‘H’ appeared, what would your response be?”*** (NOTE: make sure they are saying “same” or “different” and not just “yes” or “no”). The letters on the screen and their correct responses are: H - “none”, r - “none”, T - “different”, R - “same”, s - “different”, k - “different”, S - “same”. Keep in mind that the correct responses are not displayed on the computer screen so you will need to know them.

- i) Remind participants that although during this example it is easy to look back in the list to see what letter came two back, during the actual test they will only be seeing one letter at a time (i.e. they will have to rely on their memory to recall the two-back letter).
- ii) After working through these examples, have the participant press ‘M’ when you are both ready to move on.
- iii) The third page will contain the following instructions. Please note the use of the laminated example in the box below and read the instructions following:

As you are reading through the instructions point to the laminated example page to reinforce the test requirements. It may help to draw arrows on the laminated example page from the current letter to the letter the participant is going to be comparing.

Examiner: ***“As you just saw, your task is to keep track of the letters. For the first and second letter you will make no response, but once the 3<sup>rd</sup> letter has appeared, indicate whether it’s the same as or different from the 1<sup>st</sup> letter. When the 4<sup>th</sup> letter appears, indicate whether it’s the same as or different from the 2<sup>nd</sup> letter and so on.”***

Examiner: ***“Again, you will be making a response for EACH letter (except for the first two) and indicating if it is the same or different from the letter that came TWO letters before it.*”**

Examiner: ***“Indicate ‘SAME’ by pressing the ‘M’ key, and ‘DIFFERENT’ by pressing the ‘Z’ key.”***

Examiner: ***“Press the ‘M’ key for more instructions.”***

- iv) After the participant has pressed the ‘M’ key, the next screen will contain the following instructions which you should read regarding the practice trials the participant will complete:

Examiner: ***“Now let’s try some practice trials.”***

Examiner: ***“Remember, you will indicate ‘SAME’ by pressing the ‘M’ key, and ‘DIFFERENT’ by pressing the ‘Z’ key.”***

- v) Remember to inform participants that the task will move quickly ***“The letters will only be on the screen for a few seconds, so it’s important to make your response as quickly as possible.”*** Note that this instruction is not presented on the computer screen.

Examiner: ***“I know this task is much harder than the previous one, but nonetheless, I would like you to try to do your best.”***

Examiner: ***“To start the practice trials, press the ‘M’ key.”***

- v) After the participant has pressed the ‘M’ key, the first practice block consisting of 10 letters in length will appear.
- vi) Watch the participant’s responses to ensure that they understand the test but do not stop the practice block unless confusion or distress is expressed.
- vii) If the participant met the criterion for passing (5 or more correct items), the program will advance to the actual test, and you can move on to the directions below.
- viii) If the participant has not met the criterion for passing, the program will move to a second practice block, and then a third practice block if the criterion was still not met. The procedure for a 2nd and 3rd practice is:
  - (1) Have the participant press the spacebar when s/he is ready to continue to the second practice block if the criterion was not met during the first practice block. The second practice block also contains 10 letters.
  - (2) Have the participant press the spacebar when s/he is ready to continue on to the third and final practice block (also 10 letters) if the criterion was not met during the second practice block.

- ix) At the end of the last practice block (1st, 2nd, or 3rd), a new screen will appear with the instructions to be read below. At this point, ask the participant to reiterate for you what they are supposed to do.

Examiner: ***“Now that we’ve gone through the instructions and you’ve had a chance to practice the test, why don’t you tell me in your own words what you are supposed to do so I know I’ve made everything clear.”*** If explanation is satisfactory, read the final screen instructions.

Examiner: ***“In this test the computer will advance even if you have not made a response, so please work as quickly as you can.”***

Examiner: ***“Please ask if you have any questions.”***

Examiner: ***“When you are ready to start the actual test, press the ‘M’ key.”***

- x) The “2-back” test consists of 47 letters/trials, 45 of which the participant will respond to (no response for the first two letters). At the end of the last trial, you will see “That’s all for this part,” and then the program will automatically exit to the desktop.
- xi) **If any problems occurred during the 2-back test please note them on the Computerized Cognitive Tests Checklist Form.**
- xii) Allow the participant a 2 minute break at this point before continuing on to the next test.

#### **15.5.12.3.4 The Task-Switching Test**

**Test Description:** Participants are asked to alternate between performing 2 different tasks. For both tasks they are shown a letter/number pair (e.g., T 5) inside one box of a 4-box grid. When the stimulus appears in either of the top two boxes, the participant should indicate whether the number is odd or even. When the stimulus appears in either of the two lower boxes, s/he should indicate whether the letter is a vowel or consonant. The participant will complete three practice blocks regardless of how s/he performs. The 1<sup>st</sup> block allows the participant to practice the number task (classifying odd/even) in the top half of the test grid. The 2<sup>nd</sup> block allows the participant to practice the letter task (classifying vowels/consonants) in the bottom half of the test grid. The 3<sup>rd</sup> block allows the participant to practice performing both the number and letter task, switching between the top and bottom halves of the test grid.

**Setup:** For this task, you will have three different laminated place cards to put above the keyboard. Two of these are used only during the practice blocks as described below. The final one will be used during the third practice block and during the actual test. That place card reminds the participant that M = even/consonant and Z = odd/vowel. **There are also three laminated**

**illustrations of the upper and lower parts of the test grid containing the letter/number pairs, which you must have on hand to show the participant what the stimuli will look like.** Two of these are used only during the practice blocks as described below. The final one will be used during the third practice block and also applies during the actual test. Also have a **dry erase pen to use to clarify the instructions as needed.**

**Monitoring Participants' Performance:** As with the previous tests, be attentive to the participant's responses during the test. Watch to make sure there are no errors or problems, such as:

- i) Grid position or response confusion. Responding in a manner that suggests s/he has gotten confused as to what to do for the top vs. bottom parts of the grid by judging letters in the top of the grid (rather than numbers) and/or judging numbers in the bottom of the grid (rather than letters) .(Solution: pause the test and remind the participant of the instructions).
- ii) Key pressing issues. Mixing up the Z and M keys by mistakenly pressing the Z key for even/consonant and the M key for odd/vowel, just pressing one key repeatedly, or neglecting to press any keys at all (Solution: pause the test and explain again that s/he needs to use the M key for even/consonant and the Z key for odd/vowel), and inadvertently resting (and thus pressing) fingers on the M and/or Z key.
- iii) Response Speed Issues. Make sure that the participant is trying to perform the test as quickly and accurately as possible. If you notice that a participant's responses are especially slow, remind him/her that it is important to “**respond as quickly and accurately as possible.**” Unfortunately, in making the decision as to whether you should remind your participant that speed is important for the task, you will need to rely on your own judgment as to whether the participant is simply a slow responder across all tasks and is, in fact, going as fast as possible or if the participant has settled on a speed/accuracy tradeoff for the task switching test that favors accuracy over speed. If the participant has tended to be “slow-moving” throughout the session prior to the administration of the task switching measure, then reminding them to respond as quickly and accurately as possible may hurt their performance and so should be avoided. If instead their slow performance seems to be specific to task switching, then reminding them about speed and accuracy is the correct thing to do.
- iv) Need for a Task Interruption. If the participant is expressing confusion, you may reiterate the instructions only once using the laminated example if necessary. You cannot stop the testing more than twice for any reason once the participant has started the actual test.

**Test Timing:** This test is self-paced and will only advance to the next trial when the participant has responded, so there is no need to use the pause function if a participant becomes confused. It takes approximately 8 minutes to administer with 3 blocks of practice trials, which are each about 50 seconds in length.

### **Instructions and Screen Order for Running the “Task Switching Test”**

To begin the test, double-click on its icon (4\_taskswitching) located on the desktop. The first screen that will appear contains the following instructions, which you will read to the participant. Please note the use of the laminated example in the box below:

**Examiner:** ***“In this part of the test, you’ll see a letter and a number presented in the top two boxes of a grid.”***

Show the laminated example that consists of only the top two boxes of the grid and indicate the number as you read the following part of the instructions.

**Examiner:** ***“Your job is to classify the number as odd or even as fast as you can while remaining accurate. If the number is odd, press the Z key. If it’s even, press the M key.”***

- i) After reading through these instructions aloud, remind the participant to concentrate on the numbers s/he sees, pressing Z if the number is odd and M if the number is even. Place the laminated reminder card indicating Z=odd and M=even on the laptop.

**Examiner:** ***“Press the ‘Z’ key to start some practice trials.”***

- ii) This practice block contains 16 trials.
- iii) The next screen will contain the following instructions. Please note the use of the laminated example in the box below:

**Examiner:** ***“In this part of the test, you’ll see a letter and a number presented in the lower two boxes of a grid.”***

Here, show the laminated example that consists of only the bottom two boxes of the grid and indicate the letter as you read the following part of the instructions.

**Examiner:** ***“Your job is to classify the letter as a vowel or consonant as fast as you can while remaining accurate. Can you list the vowels for me? If the letter is a vowel, press the Z key. If it’s a consonant, press the M key.”***

- iv) While reading through these instructions with the participant, have him/her list the vowels for you (a, e, i, o, and u are used in this task – y does not appear). If the participant cannot list the vowels, write them down on a sheet of paper so that the participant can refer to them during the course of the task. Please note on the E-Prime checklist that you have done this. Also watch the participant’s performance carefully through the practice trials to see if s/he is able to distinguish vowels from consonants when seen on



the screen and record your evaluation on the E-Prime checklist. If the participant appears unable to distinguish between vowels and consonants, although the vowels have been written down, but seems non-distressed and willing to continue carrying out the task then proceed through the full test as ending early can sometimes affect a participant's self-esteem. However, if the participant is becoming distressed by having to make a distinction between vowels vs. consonants then stop the task.

- v) Remind him/her to concentrate on the letters during this practice block, pressing Z if s/he sees a vowel and M if s/he sees a consonant. Place the laminated reminder card indicating Z=vowel and M=consonant on the laptop.

Examiner: ***“Press the ‘Z’ key to start a practice trial.”***

- vi) This practice block contains 16 trials.
- vii) The next screen will contain the following instructions pertaining to the final practice block combining the number and letter task. Please note the use of the laminated example in the box below:

Examiner: ***“In this part of the test, you’ll see a letter and a number in one of four boxes of a grid.”***

Here, show the laminated example of the entire grid and indicate the letter and numbers as you read the following part of the instructions.

Examiner: ***“If the letter and number are in either of the top two boxes, your task is to say whether the number is odd or even.”***

Examiner: ***“If it’s odd, press the Z key, and if it’s even, press the M key.”***

Examiner: ***“If the letter and number are in either of the lower two boxes, your task is to say whether the letter is a vowel or a consonant.”***

Examiner: ***“If it’s a vowel, press the Z key, and if it’s a consonant, press the M key.”***

- viii) After reading through these instructions with the participant, remind him/her to use the **Z key** for identifying odd numbers in the top boxes of the grid and vowels in the bottom boxes of the grid AND use the **M key** for identifying even numbers in the top boxes of the grid and consonants in the bottom boxes of the grid. Place the laminated reminder card indicating Z=odd/vowel and M=even/consonant on the laptop.

Examiner: ***“Press the ‘Z’ key to see some examples and do some practice trials.”***

- ix) This practice block contains 32 trials.
- x) At the end of the last practice block, a new screen will appear with the instructions to be read below. At this point, ask the participant to reiterate for you what s/he is supposed to do:

Examiner: ***“Now that we’ve gone through the instructions and you’ve had a chance to practice the test, why don’t you tell me in your own words what you are supposed to do so I know I’ve made everything clear.” If satisfactory, read the final screen instructions:***

Examiner: ***“You’ll now start the actual test trials. These will be the same as what you just did. If the letter and number are in the top two boxes, indicate whether the number is odd or even.”***

Examiner: ***“If it’s odd, press the Z key, and if it’s even, press the M key.”***

Examiner: ***“If the number and letter are in the lower two boxes, indicate whether the letter is a vowel or consonant.”***

Examiner: ***“If it’s a vowel, press the Z key, and if it’s a consonant, press the M key.”***

Examiner: ***“If you have any questions, please ask.”***

- xi) Remind the participant that s/he may glance at the laminated reminder card above the keyboard to help remember what Z and M represent.

Examiner: ***“Otherwise, when you’re ready, press the ‘Z’ key to begin the actual test.”***

- xii) The test will contain 120 trials.
- xiii) After the participant has completed the last trial, the program will end and exit to the desktop. This concludes the final E-prime task.
- xiv) **If any problems occurred during the Task-switching test please note them on the Computerized Cognitive Tests Checklist Form.**

## **15.6 DATA ENTRY AND DATA UPLOAD FOR COGNITIVE ASSESSMENTS DMAQ --- TBD**

## **15.7 CERTIFICATION PROCESS FOR FIELD SITE COGNITIVE ASSESSORS**

In order to ensure the initial and ongoing quality of the cognitive data, baseline and annual certification of all cognitive assessors is essential.

Baseline certification must be confirmed prior to any data collection. Following the central training, all assessors will be required to practice administering the

complete test battery on an age appropriate volunteer. It is recommended that several practice sessions take place within one week of your initial training. When the assessor feels comfortable with the practice administrations, a formal mock assessment should be performed, on an age appropriate volunteer. The test forms and recording should be mailed to the LIFE Cognition Coordinating Center.

The Coordinating Center will review the forms and recording for accuracy in standardized administrations (reading the script verbatim, proper response to participant questions, using proper encouragement, etc.) and accuracy in scoring the paper/pencil tests.

Written feedback will be provided to assessors. If the administrations are acceptable, certification will be given and assessors will be permitted to perform the cognitive assessments on LIFE participants. If additional practice is deemed necessary, assessors will be asked to resubmit specific tests for review and ultimate certification.

For the purpose of ongoing quality assurance, the LIFE-Cognition Coordinating Center will periodically request forms and tapes to review for QA purposes. The Coordinating Center will select these administrations randomly and notify the field site by email. For this reason, each field center is required to retain the recording for each cognitive assessment. At the end of baseline testing, we will notify your site regarding disposition of the baseline recordings for each participant.

After initial certification, the Coordinating Center will re-certify all cognitive assessors on an annual basis (+/- 1 month). Working with DMAQC, the Coordinating Center will request an administration from a LIFE study visit be submitted for review. If the assessor is adhering to the LIFE protocol, re-certification will be awarded. If it is determined that an assessor is not adhering to the protocol, the Coordinating Center will either request additional administrations for review and/or provide a retraining (via phone) for the assessor.

During the course of the LIFE Study, if the field sites determine that additional cognitive assessors are needed due to staff turnover or clinic volume, certified staff at the site will train the new assessors, who will then submit a mock administration to the Coordinating Center for review and certification.

## **15.8 PROCESS FOR DEMENTIA ADJUDICATION AT FOLLOW-UP VISITS TBD**