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Manual 1
SOL-INCA
Neurocognitive Function

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Neurocognitive Function

Table of Contents

1. INTRODUCTION	3
2. FIELD CENTER PROCEDURES	3
2.1 SIX-ITEM SCREENER (PART A)	5
2.1.1 SIX-ITEM SCREENER (SCORING AND DISCONTINUATION)	6
2.2 SPANISH ENGLISH VERBAL LEARNING TEST (PART B)	7
2.2.1 SPANISH ENGLISH VERBAL LEARNING TEST (SCORING AND DISCONTINUATION)	9
2.3 WORD FLUENCY TEST (PART C)	9
2.3.1 WORD FLUENCY TEST (SCORING AND DISCONTINUATION)	11
2.4 DIGIT SYMBOL SUBSTITUTION TEST (PART D)	11
2.4.1 DIGIT SYMBOL SUBSTITUTION TEST (SCORING AND DISCONTINUATION)	14
2.5 TRAILS MAKING TEST A	14
2.5.1 TRAILS A (SCORING AND DISCONTINUATION)	15
2.6 TRAILS MAKING TEST B	16
2.6.1 TRAILS B (SCORING AND DISCONTINUATION)	17
2.7 NIH TOOLBOX PICTURE VOCABULARY TEST (PVT)	18
2.7.1 PICTURE VOCABULARY TEST (PVT; SCORING AND DISCONTINUATION)	18
2.8 EVERYDAY COGNITION (ECOG)	19
2.9 INSTRUMENTAL ACTIVITIES OF DAILY LIVING (IADL) QUESTIONNAIRE	20
2.9.1 SCORING AND DISCONTINUATION	21
2.10 NEUROCOGNITIVE SCORING SUMMARY FORM	22
3 QUALITY CONTROL ISSUES AND PROCEDURES	23
3.1 TRAINING AND CERTIFICATION	23
3.2 QUALITY ASSURANCE	24
3.3 PROXY INFORMED CONSENT	24

1. INTRODUCTION

Participants eligible (with Neurocognitive Scores at Baseline) for the ancillary Study of Latinos – Investigation of Neurocognitive Aging (SOL-INCA) will be administered a brief battery of neurocognitive tests in visit 2 of HCHS/SOL. These tests will provide new information on cognitive health and decline among Latinos, a largely understudied group. The SOL-INCA assessment of neurocognitive aging will build on the baseline study of cognitive functioning and provide new and important public health knowledge about cognitive health and decline over time.

Visit 2 cognitive measures were chosen for their broad but efficient coverage of major cognitive domains. Additional factors considered in measurement selection included validation in Hispanic samples, comparability to measures used at baseline and in previous cohort studies, feasibility with respect to the standardization of administration and scoring procedures, evidence of sensitivity in normal samples including a wide age range, and finally, for select tests, the feasibility of possible administration by phone in subsequent exams.

SOL-INCA uses several of the same neurocognitive tests from the HCHS/SOL baseline examination. These neurocognitive tests include the Six-Item Screener (**SIS**), the Spanish English Verbal Learning Test (**SEVLT**), the Word Fluency Test and the Digit Symbol Substitution (**DSS**). SOL-INCA includes new tests. These are the: Trail Making Test parts A and B (**TMT**), and the Picture Vocabulary Test (**PVT**). These quick and simple neurocognitive tests will give scientists important information that may help stall, slow down or even prevent cognitive decline.

In addition, SOL-INCA uses two questionnaires to ask participants about their cognitive health and changes over the past 10-years, and ability to manage important daily activities. They are the: 1) Everyday Cognition (**eCog**) and 2) Instrumental Activities of Daily Living (**IADL**) questionnaires.

2. FIELD CENTER PROCEDURES

The most important goal is to get the participants' **best performance** to get the information needed for our work in SOL-INCA to be a success.

A trained examiner administers the neurocognitive tests and daily activities questionnaires in a fixed order, one right after the other, during a single session in a quiet room. It is important to schedule sufficient time for participants to complete the test battery. **Additionally, it is very important that the room be away from distracting noises,** like hospital or office PA announcements, and other distractions and interruptions.

All testing for INCA should to be collected in one session. Schedulers should ensure that participants are aware of this, and that they agree to provide ample time to complete the

necessary testing. Under unusual circumstances, where respondents refuse to continue testing due to unanticipated events (e.g. sudden illness, or family emergency), participants can be rescheduled to retake all incomplete INCA tests. If possible, however, try to complete a test that is in progress. In case of a partially completed SOL-INCA test (i.e. stopping mid-test) the particular test is considered discontinued, and discontinuation procedures should be followed. The guiding principle for INCA is that we want to maximize participation with minimum participant burden and optimal study costs. Rescheduling can be costly and logistically complicated.

Printed Neurocognitive Assessment paper forms (see Appendix) are administered as described in this manual. Some of the test results are scored by the interviewer after the participant has completed the tests and left the room. Test results and Scoring data is entered in the data management system CDART (*Carolina Data Acquisition and Reporting Tool*). Six Item Screener (**SIX**, CDART code for this form), Everyday Cognition (eCog) English (CGE), and Instrumental Activities of Daily Living (IADL) English (DLE) are also entered directly into CDART

The testing order is: 1) Six-Item Screener (**SIS**); 2) Spanish English Verbal Learning Test (**SEVLT**); 3) Word Fluency test; 4) Digit Symbol Substitution (**DSS**); 5) Trail Making Test (**TMT**), and 6) Picture Vocabulary Test (**PVT**; computer administered). These tests are followed by two questionnaires: 1) Everyday Cognition (**eCog**) and 2) Instrumental Activities of Daily Living (**IADL**).

To get the **participants' best performance**, the testing conditions and procedures described below are critical because they must be the same across all four Field Centers:

- When scheduling SOL-INCA appointments, ask participants to bring reading glasses or wear their hearing aids (if they need those). Testing will be conducted in a quiet area free of interruption, as these distractions may affect test results.
- Schedulers and test administrators will always inquire if the participant uses reading glasses or wears a hearing aid. If so, these items must be worn during testing.
- The testing room must have a table with sufficient workspace and appropriate lighting for the participant to comfortably complete the DSS, PVT and TMT.
- A good quality stopwatch is necessary to time components of the cognitive function exams. The stopwatch should be simple to use, easy to read, and preferably one that allows the examiner to begin and end timing silently (some stopwatches produce a sound upon starting and stopping).
- Test administrators who are timing respondents should always try to encourage the participant to do their best by being helpful and understanding.

- Test administrators should always read scripts exactly as written.
- Each participant should be allowed to attempt every task, unless it is determined that the participant cannot do the task due to an obvious physical impairment.
- Participants are often curious as to how well they did. The interviewer should reassure these participants by telling them, *what's most important is that you try your best*. Do not indicate to the participant whether specific responses are correct or incorrect.
- Most participants will enjoy the challenge; however, some may feel uncomfortable and complain about the tests. It is important for the interviewers' attitude to be positive and supportive throughout the testing. Examiners should be sensitive to provide positive reinforcement (e.g., that's fine, or you're doing fine) when appropriate, but don't overdo it. For example, saying someone is doing great when they are not is not honest.

2.1 Six-item Screener (Part A)

The Six-Item Screener (**SIS**) (**SIX**, CDART code for this form) is derived from the Mini-Mental Status exam, which is a short mental status test that is used by many doctors and in several studies. Following the script on the paper form, the examiner briefly explains the purpose of the cognitive function portion of the HCHS/SOL examination and then proceeds with the instructions for the six-item screener.

Script: *In this part of the exam I will ask you some questions and give you a couple of short tasks that will require attention and memory.*

First, I will ask you some questions that ask you to use your memory. I am going to say three words. Please wait until I have said all three words; then repeat them. Remember what they are, because I am going to ask you to name them again in a few minutes. Please repeat these words for me: BLUE - PEAR - SOFA.

Say the words distinctly at the rate of 1.5 seconds per word.

The participant may repeat the words in any order.

If the participant repeats the word after each word is read by the examiner, at the end of the presentation say, *Tell me the three words again* and score if correct.

Do not repeat the words for the participant until after the first trial (i.e., until after all three words have been presented). If there are errors on the first trial, the examiner may repeat the words two more times.

If the participant fails to repeat all three words correctly after three attempts, this portion of the testing (i.e., recall of the three words) is discontinued. In this case, the examiner should

SOL INCA MOP 1

mark the appropriate box next to item 1: either Incorrect, or if the failed response is due to a physical limitation (e.g., hearing loss) mark Not Attempted/Refusal, or if the participant refuses to complete the task mark Not Attempted/Refusal and specify the reason. If the participant fails to repeat all three words correctly after three attempts, items 6, 7, and 8 will not be testable and should be marked as Not Attempted/Refusal. In the event that a participant refuses to complete the task (i.e., item 1 is marked as Not Attempted/Refusal), then items 6, 7, and 8 should be marked as Not Attempted/Refusal. If all words are repeated correctly (Q2) then record response to Q2 as 1 and move to administer Q3-8.

Next, the examiner asks the orientation items and records the appropriate response.

Script: *What year is this?*

Script: *What month is this?*

Script: *What is the day of the week?*

Record the appropriate response next to each item.

Do not offer extra help or provide any feedback as to whether a response is correct or incorrect.

Do not wait too long for a response (~ 15 seconds) before prompting for a response by repeating the question. After the question is repeated wait ~ 10 seconds for a response before moving on to the next item. The lack of a response after a reasonable period is marked as Not Attempted/Refusal.

Ask the participant to recall the three words presented earlier.

Script: *Now, what were those three words I asked you to remember?*

Record the appropriate response next to each item.

The words may be repeated in any order.

Recalled words are considered correct whether stated in Spanish or English regardless of the language in which the original words were provided.

2.1.1 Six-item Screener (Scoring and Discontinuation)

Questions 1 and 2 are administrative. Filled to reflect task attempt, reason for lack of attempt, and whether the memory words were repeated correctly. Items 3-8 on the SIS are scored as correct/self-correct, incorrect/don't know, or not attempted/refusal. An incorrect response includes a response of I don't know or I can't remember. When no response is received after 30 seconds, mark it "Not Attempted/Refusal". If the SIS memory task is not attempted due to a

physical impairment (such as hearing loss) check that the task was not attempted, and specify reason. Additionally check Not Attempted/Refusal for the individual items.

2.2 Spanish English Verbal Learning Test (Part B)

The SEVLT is a measure of new learning and verbal memory. The participant is asked to recall a list of 15 common words over three trials. Recall of the words occurs after a short delay, during which a new (distracter) list of words is presented.

The first 15-item word list is presented in three learning trials.

Script: *Next, I am going to read a list of words. I want you to listen carefully and try to remember the words as I read them. When I stop, I would like you to recall as many of the words as you can in any order. You may know some of the words by a different name, but I want you to try to remember the exact words that I say. You might not be able to remember all of the words so just do the best you can. You do not have to recall the words in the same order that I read them. The words are...*

Say each word distinctly at the rate of ~ 1.5 seconds per word.

Script: *Now tell me all of the words you can remember, please.*

Following these instructions, start the stopwatch. Timing should be discrete to avoid creating anxiety or a sense of time pressure.

Check off all the words recalled.

The participant may repeat the words in any order.

Recalled words are considered correct if stated in **either English or Spanish**.

Once the participant has produced as many words as he/she appears able to recall, provide one prompt for additional items before going on to Trial 2.

Do not allow more than 60 seconds for recall for any trial, simply say *Let's try it again*.

Repeat the list for Trial 2.

Script: *I am going to read the same list of words to you again. I want you to try to remember as many of the words as you can, including those you have recalled before. When I stop I want you to tell me as many of the words as you can remember.*

Read the 15-item word list.

SOL INCA MOP 1

Script: *Now tell me all of the words you can remember.*

Discretely start the stopwatch.

Check off all the words recalled.

Once the participant has produced as many words as he/she appears able to recall, provide one prompt for additional items before going on to Trial 3.

Do not allow more than 60 seconds for recall of Trial 2.

The word list is repeated for a final time in Trial 3.

Script: *I will read the same words once more. Listen carefully and when I finish tell me as many of the words as you can remember.*

Present the word list.

Script: *Now tell me all of the words you can remember.*

Discretely start the stopwatch.

Check off all the words recalled.

Once the participant has produced as many words as he/she appears able to recall, provide one prompt for additional items before presenting the Distracter list.

Do not allow more than 60 seconds for recall of Trial 3.

Next, the new (Distracter) list of 15 shopping items is presented.

Script: *I am going to read you a different list of words. This time, I want you to repeat each word out loud after I read it.*

Present each word and pause for the participant to repeat it. If the participant does not repeat a word, prompt for the correct response.

Following the presentation and repetition of the distracter items immediately ask the participant to recall the 15 items from the first list presented.

Script: *Now, I want you to tell me as many of the words from the first list that I read to you as you can remember.*

Discretely start the stopwatch.

SOL INCA MOP 1

Do not repeat the first list.

Check off all the words recalled.

Once the participant has produced as many words as he/she can recall, provide one prompt for additional items.

Do not allow more than 60 seconds for recall.

It is very important that the full 60" for responses be allotted before discontinuing.

2.2.1 Spanish English Verbal Learning Test (Scoring and Discontinuation)

The number of correctly recalled words for each of the three learning trials (Trials 1-3) and the recall trial (Trial 5) are recorded on the Neurocognitive Summary Scoring Form by the examiner after the participant has left the exam area.

Words may be recalled in any order.

Recalled words are considered **correct only for English or Spanish words**.

Participants with memory problems especially may refuse to respond. Ask the participant to *Just try your best*. The SEVLT may be discontinued due to participant refusal or if the examiner determines that the participant is unable to perform the task due to a physical impairment such as hearing loss. If discontinued, the reason is recorded on the Neurocognitive Scoring Summary Form.

2.3 Word Fluency Test (Part C)

The Word Fluency Test is a measure of verbal fluency and thinking. The participants are asked to produce as many words as possible that begin with the letters F and A within a time limit of 60 seconds for each letter, avoiding proper nouns (e.g., David or Dallas), variations (dance, dancing, danced), plurals (e.g., dances), and repetitions. **English or Spanish words are acceptable.**

Explain the task to the participant.

Script: *On this next task, I will say a letter. Then I want you to tell me as many different words as you can think of, as fast as you can, that begin with that letter. You may tell me words in English or Spanish so long as they are different words. Leave out names of people, names of places, and numbers. For example, if I were to say T, you **would not** say words, like 'Thomas,' 'Texas,' or the number 'Ten.'* But **you could say** words like 'table,' 'take,' or 'turtle.'

Pause.

SOL INCA MOP 1

Script: *Also, do not use the same word again with a different ending. For example, if you said take, then you could not say takes, or taking. These would all be considered the same word. Are you ready?*

Pause.

Script: *Tell me as **many words** as you can that start with the letter **F**. I will tell you when to stop. Ready? Go!*

Discretely start the stopwatch and record the participant's responses verbatim.

If the participant is working slowly or cannot produce more words, wait quietly for ~ 10 seconds. After 10 seconds of silence prompt for more words, saying: *Can you think of any other words that begin with the letter F?*

Do not stop the test until the entire 60 seconds is over.

A participant may stop producing words because he/she feels he/she made an error (e.g., repeated a word or said a proper name). In this instance, prompt the participant to continue, saying: *that's okay; keep going.*

The examiner should never interrupt the exam to correct sporadic errors.

The examiner may clarify the instructions only when the participant has clearly misunderstood the instructions and is only providing incorrect words, like proper names or only listing numbers. In the case of three or more consecutive incorrect words, the examiner should clarify the instructions, saying: *Tell me words that start with F but do not include names of people (or proper names of places or numbers depending on the error).*

While recording the words, if the examiner cannot keep up with the words produced and misses a word, but is certain that the participant produced an admissible word, place an x on the line to indicate the participant should receive credit for the word.

After 60 seconds has passed, the examiner stops the test, provides encouragement, and states the next letter.

Script: *Thank you. Now, tell me as many words as you can that start with the letter A. Keep going until I will tell you to stop. Ready? (Wait 2 seconds) Go!*

Discretely start the stopwatch and record the participant's responses verbatim.

After 60 seconds has passed, the examiner stops the test.
Remember to clarify any words that were unclear during the time of the test.

2.3.1 Word Fluency Test (Scoring and Discontinuation)

After the participant has left the room, the examiner must review all the words for correctness. The examiner should finish writing out any words that were not completely written out during the exam (it's sometimes hard to keep up with some people). If you are unable to spell the word, ask for help or write it out as best you can. Check any unusual words (sorry, swear words count) in the dictionary (only after the participant has left the room).

Draw a single straight line through any incorrect words (proper nouns, variations, like changing word ending, e.g. fish, fished), plurals, and repetitions. Record the number of correct words for each letter on the Neurocognitive Scoring Summary Form.

Words like anyone, anything, and anybody are counted as separate words. Homonyms like ant and aunt may be counted if given consecutively otherwise it is considered a repetition and only counted as one word.

Homophones (i.e., words that sound like they are spelled with F or A but actually begin with another letter) are inadmissible.

Admissible words may be produced in Spanish or English regardless of the language in which the instructions were provided. Words from other languages (e.g., apropos) are also counted; however it is up to the examiner to verify the word in cases where the examiner is not familiar with a given word. Each field center should refer to the same standard dictionary in the clinic. Cases where the examiner is unclear about scoring should be referred to the SOL-INCA staff for clarification.

The Word Fluency Test may be discontinued due to participant refusal, task difficulty (i.e., meaning the participant never understood the instructions), or if the examiner determines that the participant is unable to perform the task due to a physical impairment such as hearing loss. If discontinued, the reason is recorded on the Neurocognitive Scoring Summary Form.

2.4 Digit Symbol Substitution test (Part D)

The Digit Symbol Substitution (DSS) test (also referred to interchangeably as DSST) is a measure of psychomotor speed and sustained attention. In this task, the participant is asked to translate numbers (1-9) to symbols using a key provided at the top of the test form.

Present the instructions deliberately and at a slow pace.

Hand the participant a pencil without an eraser. Place the digit symbol form in front of the participant, point to the key above the test items and read the script

Script: *Please, look at these boxes (point). Notice that each box has a number in the upper part and a special mark in the lower part. Each number has its own mark.*

SOL INCA MOP 1

Point to 1 and its mark, then to 2 and its mark.

Script: *Now, look down here to where the boxes have numbers in the top part, but the squares at the bottom are empty.*

Point to the sample items.

Script: *I want you to put in each of the empty squares the mark that should go there, like this.*

Point to the first sample item, then to the mark below the 2 in the key.

Script: *Here is a 2; the 2 has this mark (pointing). So I put it in this square, like this.*

Write in the symbol in the first sample square. Then say:

Script: *Here is a 1; the 1 has this mark.*

Point to the second sample item, then to the mark below the 1 in the key.

Script: *So I put it in this square.*

Write in the symbol in the second sample square. Then say:

Script: *This number is 3; the 3 has this mark.*

Point to the third sample item, then to the mark below the 3 in the key.

Script: *So I put it in this square.*

Write in the symbol in the third sample square.

After marking the first three samples items, say:

Script: *Now, you fill in the squares up to this heavy line.*

If the participant makes an error on a sample item, correct the error immediately and review the use of the key. Continue to help (if necessary) until the seven sample items have been filled in correctly. Do not proceed with the test until the participant clearly understands the task. When the participant fills in a sample item correctly, offer encouragement by saying: *yes or right.*

When the sample items have been completed successfully, say:

SOL INCA MOP 1

Script: *Yes, now you know how to do them.*

During the sample exercise, look to see if a left-handed participant blocks or partially blocks the key when filling in the marks. If this occurs, fold a separate template so that only the key is exposed and place it next to the participant's worksheet on the participant's right-hand side so that the extra key is aligned with the one blocked by the participant's left hand. Have the participant use the separate key to complete the sample items and to take the actual test.

To begin the formal test, say:

Script: *When I tell you to start, you do the rest of them.*

Point to the first test item and say:

Script: *Begin here and fill in as many squares as you can, one after the other, without skipping any. Keep working until I tell you to stop. Work as quickly as you can without making mistakes.*

Sweep across the first row with your finger and say,

Script: *When you finish this line, go on to this one.*

And point to the first item in row 2.

Script: *Ready? (pause) Go!*

Discretely begin timing.

If the participant omits an item or starts to do only one type (e.g., only the 1 s) say,

Script: *Do them in order. Don't skip any.*

Point to the first item omitted and say:

Script: *Do this one next, please.*

If the participant gets to the end of a line and stops, say:

Script: *Please go on to the next line.*

Give no further assistance except (if necessary) to remind the participant to continue until instructed to stop.

The examiner must sit quietly and minimize movements to avoid distracting the participant during this test.

Timing must be precise. At the end of 90 seconds, say:

Script: *Stop. That's good, thank you.*

2.4.1 Digit Symbol Substitution test (Scoring and Discontinuation)

After the participant has left the room, the examiner scores the DSS. Using the DSS scoring template, record 1 point for each correctly drawn symbol completed within the 90-second time limit and record this number on the Neurocognitive Scoring Summary Form.

A response is scored as correct if it is clearly identifiable as the keyed symbol, even if it is drawn imperfectly (e.g., v instead of u-shape) or if it is a spontaneous correction of an incorrect symbol.

Credit is not given for items completed out of sequence (e.g., doing all the 1's). Blank spaces between two completed items receive no credit.

If there is more than one symbol in the box, and one is correct, give the participant credit. The seven sample items are not included in the participant's score.

The DSS may be discontinued due to participant refusal, task difficulty (e.g., the participant never fully understood the instructions), or if the examiner determines that the participant is unable to perform the task due to a physical impairment such as a motor or visual problem. If discontinued, the reason is recorded on the Neurocognitive Scoring Summary Form.

2.5 Trails Making Test A

The TMT is a timed task in which participants connect letters and numbers in sequence as quickly as possible. TMT measures attention, sequencing, mental flexibility, and visual search and motor function.

In TMT A, the participant is asked to draw a line and connect a series of numbers (from 1-25) as quickly as possible. Prior to each test part, the participant is given a sample test to demonstrate the task.

The score for TMT A is the number of seconds required to complete the task. A maximum of 240 seconds (4 minutes) and 5 errors is allowed.

Present the instructions deliberately and at a slow pace.

SOL INCA MOP 1

The administrator will start with a sample of the TRAILS A test, and present to the participant a black pen, a TRAILS A sample tracing sheet and a pencil.

Script: *On this page (point) are some numbers.*

Begin at number 1 (point to 1) and draw a line from 1 to 2 (point to 2), 2 to 3 (point to 3), 3 to 4 (point to 4), and so on, in order, until you reach the end (point to the circle marked end).

Draw the lines as fast as you can.

Ready? Go!

When finished say: *Good.*

Script: *Let's try the next one.* (If the participant makes a mistake, point out the error and explain it...)

Now you try it (and repeat the original directions, starting with Begin at number 1...)

Once this is done the administrator will offer the participant the complete TRAILS A test sheet and read the following script deliberately and at a slow pace:

Script: *On this page are more numbers from 1 to 25.*

Do this the same way: Begin at number 1 (point to 1) and draw a line from 1 to 2,(point to 2), 2 to 3 (point to 3), 3 to 4 (point to 4), and so on, in order, until you reach the end (point to end).

Remember; work as fast as you can.

Ready? Go!

Call all errors to the participant's attention immediately (draw two small dashes through the incorrect line) and have the participant proceed from the point the mistake occurred.

Do not stop timing.

If the participant makes 5 errors or exceeds 4 minutes, stop the test.

Record errors and time. At the end, say, *That's fine, or good.*

2.5.1 Trails A (Scoring and Discontinuation)

After the participant has left the room, the examiner scores the TRAILS A. Using the TRAILS A scoring template, record 1) the total time to complete the test in minutes and seconds (max of

4 minutes), and 2) the total number of errors committed by the participant (max of 5). Both numbers will be recorded on the Neurocognitive Scoring Summary Form.

To count the number of errors, and use the number of small dashes that the administrator drew through the incorrect lines (mistakes) at the time of the test.

The TRAILS A test may be discontinued due to participant refusal, task difficulty (e.g., the participant never fully understood the instructions), if the examiner determines that the participant is unable to perform the task due to a physical impairment such as a motor or visual problem, and if the participant makes 5 errors or exceeds 4 minutes, stop the test. If discontinued, the reason is recorded on the Neurocognitive Scoring Summary Form.

2.6 Trails Making Test B

In TMT B, the participant is asked to draw a line and connect a series of numbers and letters, alternating between a given number and letter (e.g., 1 to A, A to 2, 2 to B, B to 3, etc.) as quickly as possible. Prior to each test part, the participant is given a sample test to demonstrate the task.

The score for TMT B is the number of seconds required to complete the task. A maximum of 240 seconds (4 minutes) and 5 errors is allowed.

Present the instructions clearly and at a slow pace.

The administrator will start with a sample of the TRAILS B test, and present to the participant a black pencil, a TRAILS B sample tracing sheet and a pencil.

Script: *On this page are some numbers and letters.*

Begin at number 1 (point) and draw a line from 1 to A (point to A), A to 2 (point to 2), 2 to B (point to B), B to 3 (point to 3), 3 to C (point to C) and so on in order until you reach the end (point to end).

Remember, first you have a number, then a letter, then a number, then a letter, and so on.

Do not skip around, but go from one circle to the next in the proper order.

Draw the lines as fast as you can. Ready? Go!

If there are any mistakes on the sample, the administrator will review the instructions.

Script: *Let's try the next one. (If the participant makes a mistake, point out the error and explain it...) Now you try it, (and repeat the original directions, starting with Begin at number 1...)*

Once this is done the administrator will offer the participant the complete TRAILS B test sheet and read the following script deliberately and at a slow pace:

Script: *On this page are some numbers and letters.*

Begin at number 1 (point) and draw a line from 1 to A (point to A), A to 2 (point to 2), 2 to B (point to B), B to 3 (point to 3), 3 to C (point to C) and so on in order until you reach the end (point to end).

Remember: first you have a number, then a letter, then a number, then a letter, and so on.

Do not skip around, but go from one circle to the next in the proper order.

Draw the lines as fast as you can. Ready? Go!

The administrator will call all errors to the participant's attention immediately (and draw two small dashes through the incorrect line) and have the participant proceed from the point the mistake occurred.

The administrator will not stop timing.

If the participant makes 5 errors or exceeds 4 minutes, the administrator will stop the test.

Record the number of errors and time.

At the end, the administrator will say, *That's fine, or, well done.*

2.6.1 Trails B (Scoring and Discontinuation)

After the participant has left the room, the examiner scores the TRAILS B. Using the TRAILS B scoring template, record 1) the total time to complete the test in minutes and seconds (max of 4:00), and 2) the total number of errors committed by the participant (max of 5). Both numbers will be recorded on the Neurocognitive Scoring Summary Form.

To count the number of errors, use the number of small dashes that the administrator drew through the incorrect lines (mistakes) at the time of the test.

The TRAILS B test may be discontinued due to participant refusal, task difficulty (e.g., the participant never fully understood the instructions), if the examiner determines that the participant is unable to perform the task due to a physical impairment such as a motor or visual problem, and if the participant makes 5 errors or exceeds 4 minutes, stop the test. If discontinued, the reason is recorded on the Neurocognitive Scoring Summary Form.

2.7 NIH Toolbox Picture Vocabulary Test (PVT)

Instructions (for PC version):

Script: *You are going to be asked the meaning of some words. For each item, you will hear a word and see four pictures on the screen. Click on the picture that you think best matches the meaning of the word that was said. If you are not sure, make your best guess. If you need to hear the word again, click on the button that has a picture of an EAR (screen icon), also called the PLAY AGAIN button. After you make your choice and click on a picture, the machine will automatically go to the next word and pictures. You will keep hearing words and clicking on pictures until you are done. If you want to change your choice, click on the GO BACK button and review or change your choice. Each time you make a choice, the computer automatically gives you a new word and a new set of pictures. Remember, if you are not sure of an answer, make your best guess. Tell me when you are ready to start, then click on the NEXT button.*

Two practice items are automatically administered by the computer. Allow the participant up to three chances to answer this practice item correctly. After three unsuccessful attempts, *click on the correct picture on the computer screen and say:*

This is a banana or This is a spoon.

Review the task with the participant, saying:

Remember, you will hear a word and then you will see four pictures. One of the pictures will show what the word means. Click on that picture; then you will hear another word and see four more pictures. Again, click on the picture that shows what the word means. If you don't know an answer, make your best guess. Any questions? (Answer the questions.)

Script: *Now, we're going to do some more. Some of the words will be easier and some will be more difficult. Just try your best on each question. When you're ready, click on the NEXT button to start.*

Remember: If a participant has difficulty using the PC, he/she may point and the examiner can operate the PC's mouse for the participant. If the participant says that he /she does not understand the word after several repetitions, the examiner may say the word one more time.

The computer will record and store all responses until the PVT is completed and securely transmitted to the data central.

2.7.1 Picture Vocabulary Test (PVT; Scoring and Discontinuation)

Description: The PVT is a measure of receptive vocabulary that is administered in a computerized adaptive format. That is, the next question a participant receives depends on his/her response to the previous question; Computer Adaptive Testing (CAT) ensures a test that is tailored to the participant's needs. The respondent is presented with an audio recording of a

word and four photographic images on the computer screen and is asked to select (click on) the picture that most closely matches the meaning of the word. This test takes approximately four minutes to administer and is recommended for ages 3-85.

The PVT is part of the NIH toolbox and will be administered on a dedicated system. Field center staff will be responsible to enter participants' age and education information when they administer the PVT. PVT collects handedness (left/right) information from the participant. This information is needed for the PVT computer application.

Scoring Process: PVT scoring is automatic and will be uploaded directly to a centralized database. Item Response Theory (IRT) is used to score the PVT. A score known as a theta score is calculated for each participant; it represents the relative overall ability or performance of the participant. A theta score is very similar to a z-score, which is a statistic with a mean of zero and a standard deviation of one. Age-adjusted, fully adjusted and unadjusted scale scores, as well as a national percentile rank that corresponds to the age-adjusted scale score, are provided for the PVT. In addition, the theta score is converted to a Computed Score that appears in the Assessment Scores output file available through Assessment Center. (This file and its components are described in detail in Appendix B1.) The Computed Score for PVT ranges from roughly 200 to 2000 and can be used for simple vocabulary ability comparisons over time.

The questionnaire may be discontinued due to participant refusal, or participant indicating difficulty in completing questionnaire (e.g., the participant never fully understood the instructions), and if the examiner determines that the participant is unable to continue. If discontinued, the reason for discontinuation will be recorded. Three reasons for discontinuation are available for the questionnaire administrator (1=Refused; 2=Task Difficulty; 3=Impairment). Task difficulty is appropriately marked in cases where the examiner feels compelled to discontinue a test, for example if a participant appears particularly frustrated by a test or does not appear to comprehend the instructions to a test, but where no obvious physical limitation can otherwise explain the participant's poor performance.

Discontinuation information for the PVT should be inserted into the SOL-INCA Eligibility and Recruitment Form. Question 2 allows for registering whether the PVT test was administered (Yes, No), and includes additional slots for registering information on whether the test was a) discontinued, and b) the reason for discontinuation.

2.8 Everyday cognition (eCog)

The eCog is a brief questionnaire that asks participants to rate any changes in memory and thinking over the past 10-years. It is **very important that the participant understands that he/she is comparing his/her current cognitive functioning with 10-years ago**. Following the script, the examiner briefly explains the eCog 10-year comparison purpose and then proceeds with the instructions of the actual eCog test.

Introductory Script: *“Please rate your CURRENT ability to perform daily tasks compared with your ability to do the same task 10 years ago. In other words, try to remember how you were 10*

years ago and tell me any changes you have noticed in your ability to do the task. Rate the changes based on the following four-point scale: 1) better or there is no change in my ability compared to 10 years ago 2) I occasionally perform the task worse than 10 years ago, but not all the time 3) I consistently perform the task a little worse than 10 years ago 4) I consistently perform the task much worse than 10 years ago.”

The interviewer will read the stem question first.

Next, the interviewer will read each of the twelve items in order.

After each item is read, the interviewer will provide all **READ ALL ANSWER CHOICES** slowly and deliberately, and record the participants answer.

The interviewer should not volunteer the “Don’t Know” or “Not Applicable” option, but will record the answer as such if the participant states it.

The questionnaire may be discontinued due to participant refusal, or participant indicating difficulty in completing questionnaire (e.g., the participant never fully understood the instructions), and if the examiner determines that the participant is unable to continue. If discontinued, the reason for discontinuation will be recorded. Three reasons for discontinuation are available for the questionnaire administrator (1=Refused; 2=Task Difficulty; 3=Impairment). Task difficulty is appropriately marked in cases where the examiner feels compelled to discontinue a test, for example if a participant appears particularly frustrated by a test or does not appear to comprehend the instructions to a test, but where no obvious physical limitation can otherwise explain the participant's poor performance.

2.9 Instrumental Activities of Daily Living (IADL) Questionnaire

The IADL questionnaire provides a tool to assess overall individual functioning and can be used for both clinical purposes and in large community dwelling population surveys.

There are 7 IADL questions that are used to assess a participant’s ability to function independently. In response to each question, study participants will report their ability to perform the specific task independently (i.e., without help), with some help, or not (able to perform the task) at all.

The interviewer will use the following script prior to questions administration:

Script: *Now I’d like to ask you about some of the activities of daily living, things that we all need to do as part of our daily lives. I would like to know if you can do these activities without any help at all, or if you need some help to do them, or if you can’t do them at all.*

The questionnaire administrator will **read all questions/items in the order presented on the form.**

The questionnaire administrator will read the stem question and provide examples (included in parentheses on the questionnaire form).

The questionnaire administrator will **READ ALL ANSWER CHOICES** slowly and deliberately.

The questionnaire administrator should not volunteer the “No Answer” option, but will record the answer as such if the participant refuses, does not respond, or states that they do not know.

On certain questions, the participant might indicate that they do not do certain activities in question. For example, when asked if they “can prepare their own meal” the participant might respond “I don’t or never cook”. In this case, the questionnaire administrator will say “if you had to prepare your own meal, could you do it” and then read the response options.

In the case of Medication (Question 6), if the respondent answers “I don’t take any medication” then the questionnaire administrator will score a 2 (without help) since no help is needed.

For question 8,

If the participant has reported any lack of independence (any of questions 1-7 were answered as 1=“Need for Some Help” or 0=“Unable to Perform a Task”), ask the additional question 8 starting with: “You mentioned that you needed help with one or more tasks...”

Is that because of problems with 1) attention, concentration or remembering? Or 2) physical problems. A third option “don’t know” is also available. However, the interviewer should not volunteer the “Don’t Know” option, but will record the answer as such if the participant states it.

The intent of this question is to determine if, for example, the inability to use a telephone is not due to a hand injury or missing a limb. We are trying to assess how much of self-care problems are due to cognition, not physical impairment.

The OARS IADL Questionnaire can take about 5 minutes to complete.

2.9.1 Scoring and Discontinuation

The OARS IADL subcomponent includes a question that gauges the source/cause for reported difficulties in performing IADL tasks. Specifically, a participant who scores a 1 or 2 (i.e., need for some help, unable to perform a task) on any of questions 1-7 will trigger the additional question 8 that assess whether the impairment is due to any “attention, concentration or remembering,” or “physical problems (1, 2). A third option for “Don’t know” is also available

but the interviewer should not volunteer the “Don’t Know” option, but will record the answer as such if the participant states it.

The questionnaire may be discontinued due to participant refusal, or participant indicating difficulty in completing questionnaire (e.g., the participant never fully understood the instructions), and if the examiner determines that the participant is unable to continue. If discontinued, the reason for discontinuation will be recorded. Three reasons for discontinuation are available for the questionnaire administrator (1=Refused; 2=Task Difficulty; 3=Impairment). Task difficulty is appropriately marked in cases where the examiner feels compelled to discontinue a test, for example if a participant appears particularly frustrated by a test or does not appear to comprehend the instructions to a test, but where no obvious physical limitation can otherwise explain the participant's poor performance.

2.10 Neurocognitive Scoring Summary Form

The Neurocognitive Scoring Summary Form (see Appendix) is completed after the participant has finished the cognitive tests and left the exam area.

All testing for INCA should to be collected in one session. For partial completion of testing in case of emergency or sudden illness see procedure in Section 2 paragraph 2 above.

Item 0a: Record the date of data collection.

Item 0b: Record the code number of the interviewer completing this form.

Questions 1-9 (Part A: Six Item Screener) have already been recorded by the examiner on Page 1 of the Neurocognitive Assessment booklet and are entered into the DES as they appear on Page 1.

The SEVLT (Part B), Word Fluency Test (Part C), and Digit Symbol Substitution Test (Part D) are each scored after the participant has left the exam area and are recorded by the examiner on the Neurocognitive Scoring Summary Form.

If any test scores are permanently missing because part of the battery was skipped or discontinued, enter discontinued or skipped in those fields. Further details regarding discontinued tests are recorded in Item 16 (a-c).

Items 10-13: Record the number of correct words recalled (checked off by column on the SEVLT form) for each of the three learning trials (Trials 1-3) and the recall trial (Trial 5). Refer to section 2.2.1 for scoring instructions.

Items 14-15: Record the number of acceptable words produced for each letter, F and A. Refer to section 2.3.1 for detailed scoring instructions.

SOL INCA MOP 1

Item 16: Apply the DSS scoring template to the response form and record the number of correct symbols. Refer to section 2.4.1 for detailed scoring instructions.

Item 17a-17b: For the TRAILS A record 1) the total time to complete the test in minutes and seconds (max of 4:00), and 2) the total number of errors committed by the participant (max of 5).

Item 18a-18b: For the TRAILS B record 1) the total time to complete the test in minutes and seconds (max of 4:00), and 2) the total number of errors committed by the participant (max of 5).

Item 19: Record the language in which the tests were administered. If parts were given in both English and Spanish, record the predominant language used.

Item 20 (a): Record whether cognitive tests parts B-F, were discontinued. If none was discontinued, the Neurocognitive Summary Form is complete. If any tests were discontinued, note which tests (Item 20b) and the reason(s) (Item 20c) as either refusal, task difficulty, or physical impairment (e.g., visual loss, hearing loss, limb or motor problem). Task difficulty is appropriately marked in cases where the examiner feels compelled to discontinue a test, for example if a participant appears particularly frustrated by a test or does not appear to comprehend the instructions to a test, but where no obvious physical limitation can otherwise explain the participant's poor performance.

3 QUALITY CONTROL ISSUES AND PROCEDURES

3.1 Training and Certification

Prior to the first SOL-INCA visit, test administrators will learn to do the test procedures consistently across our four Field Centers in Bronx, Chicago, Miami, and San Diego. Following training, examiners will obtain approval from the Field Center lead examiners or study coordinators and submit three audio-recorded SOL-INCA protocols along with copies of the paper protocols to the SOL-INCA Lead Center at the Michigan State University for review. Certification assessments should not be performed on SOL-INCA participants. Examiner certification for the SOL-INCA exam is achieved by the successful administration and scoring of the three certification assessments reviewed and approved by the SOL-INCA Lead Center.

The Field Center lead examiner or study coordinator, under the supervision of the SOL-INCA Lead Center Principal Investigator, is responsible for the basic training of all new field center examiners. Following basic training and approval by the Field Center study coordinator, new examiners will submit three audio-recorded neurocognitive assessments for review and approval by the SOL-INCA Lead Center for certification.

Maintaining proficiency in the administration of the neurocognitive module measures and questionnaires requires regular exposure to the protocol. In order to maintain certification, examiners will administer the neurocognitive measures at least once per month.

Recertification will be performed annually and requires the successful administration and scoring of one audio-recorded neurocognitive examination reviewed and approved by the SOL-INCA Lead Center. A participant assessment may be submitted for recertification purposes.

3.2 Quality Assurance

Several procedures are in place to monitor data quality.

With participant approval, random weekly assessments are routinely audio-recorded for quality control. Consent forms now include a dedicated section requesting participant agreement for audiotaping. During the first six months of the study, audio-recorded exams and associated paper protocols for each examiner will be reviewed by the SOL-INCA Lead Center to ensure appropriate pacing and technique, adherence to protocol, accuracy of recorded responses and scoring. This will keep consistency across all four Field Centers. Notes about any inconsistencies and deviations from the established protocol will be sent to the Field Center lead examiner or study coordinator. After the initial 6-month period, one audio-recorded exam and associated paper protocol for each examiner will be reviewed for accuracy and adherence to protocol by the SOL-INCA Lead Center.

General feedback pertaining to all examiners is provided on monthly conference calls involving field center study coordinators. These calls also provide an opportunity to discuss and problem-solve any exam issues that arise.

The SOL-INCA Lead Center will conduct an annual site visit to the Field Centers to observe examiner performance and ensure an optimal testing environment.

Test score means and standard deviations are regularly tracked and reported for each examiner by the Data Coordinating Center allowing detection of outliers and investigation of possible systematic differences by examiner.

3.3 Proxy Informed Consent

Participants in the SOL-INCA study at time of consent are either presenting at the HCHS/SOL Visit 2 clinic for their protocol driven Visit 2 exam or are “call-backs” – those participants who have already completed their Visit 2 examinations and are returning to the clinic solely to complete the SOL-INCA interviews and tests. In either instance the participant will have already signed the HCHS/SOL Visit 2 Informed Consent Document.

In the HCHS/SOL Visit 2 Study those deemed to have diminished capacity to provide informed consent (*HCHS2 MOP2 Field Centers Procedures Manual*, Section 5.5 Informed Consent by Proxy) require a proxy to complete the Visit 2 consent on their behalf, to participate in the

second visit of the SOL study. In HCHS/SOL, this person is called the “**proxy informant.**” The “**proxy informant**” can assist the participant responding to interview questions. HCHS/SOL uses the Six-Item Screener to help identify participants who may need assistance in responding accurately to interviews. Any participant requiring a “proxy informant” in the Parent Study will also have that same requirement in order to participate in SOL-INCA.

In accordance with HCHS/SOL procedures participants who take part in Visit 2 under a consent by proxy are offered INCA procedures since they are not preempted by a safety exclusion. Unlike the Parent Study, because of the nature of the SOL-INCA study (the focus on participant cognitive function) SOL-INCA will not use alternate informant provided information. In SOL-INCA the proxy will be used solely during the consenting process.

Both the Parent Study and SOL-INCA require both the proxy consentor and the participant to sign the consent form.