

# **Diabetes Prevention Program Outcomes Study**

## **Neurocognitive Function Manual**

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### 1. INTRODUCTION

Participants will be administered a brief battery of neurocognitive tests in the baseline DPPOS examination and again in approximately 18 months. The first assessment will establish a baseline for cognitive functioning in DPPOS participants, which with repeated cognitive measurements in the subsequent exam will provide the opportunity to identify risk factors associated with change in cognitive functioning over time.

These cognitive measures were chosen for their broad but efficient coverage of major cognitive domains. The measures of cognitive function administered in the DPPOS baseline examination include the six-item screener, the Spanish English Verbal Learning Test, the Word Fluency Test of the Multilingual Aphasia Examination (letters F or P {Spanish speakers} and Animal Category), and the Digit Symbol Substitution Test of the Wechsler Adult Intelligence Scale-Revised (WAIS-R). These measures tap five cognitive domains: global mental status, verbal learning and memory, word fluency, and psychomotor speed, respectively.

The following are general guidelines for interviewing, procedures for handling special difficulties, and special considerations for conducting a cognitive assessment.

The ultimate goal of the research interview is standardized and reliable collection of data. The interviewer plays an important role in serving as the human conduit of information from participants to the database. The way the interviewer conducts the interviews both facilitates and standardizes the gathering of the data. The following are some of the important roles of the interviewer.

### GENERAL INTERVIEWING GUIDELINES

#### Represent the Study

As an interviewer, you are the participant's link with the research project. While you do not act alone in the relationship with the participant, an unpleasant interview experience could tip the balance for a participant who is beginning to lose interest or is contemplating withdrawal.

- Always be polite. Remember, you represent the project and your co-workers. Call participants by name to make their experience more personal. Use titles (Ms., Mrs.) and last names unless the participant requests otherwise.
- Impart to the participants respect for the confidentiality of the information they provide by focusing your attention on them alone. Obviously taking calls on your cell phone, for example, would be inappropriate, unless the calls are related to an emergency.
- Leave the participant with an overall feeling of well-being. The goal is to make the participant's encounters pleasant enough to be worth repeating.

- Be friendly but not chummy. Use a manner of speaking that is natural to you. If your usual style is too casual, then with your supervisor's help, develop a genuine firm and even manner.
- Approach the interview with pleasure and assume that the participant will do the same. Most people like being asked about themselves and their well-being; you are giving participants an opportunity to express themselves.
- With respect to dress code, neatness and professionalism are the rule.
- When appropriate, keep notes on your conversations with participants for use by other research staff that might be useful for future scheduling and other research-related interactions

### **Manage the Interview**

Control and focus the interview without dominating the participant. Your job is to get information, not to show what you know. The participant's answers to the questions are important. You help to convey that importance by your professional demeanor, by maintaining control of the situation, and by focusing on the content of the interview. Be politely firm and businesslike; timidity can signal lack of confidence. Insecurity and hesitance could lead to biased responses.

### **Collect Data**

Each item has a research intention, and you must understand what this research intention is for each of the items. This is critically important because the research intention of certain items may be different across studies and can be different than clinical settings. Strive to understand the research intention of the data you are collecting (the purpose and meaning of the data to be collected via each item on the forms). If you do not understand, ask the coordinator for clarification.

- Take no personal stake in the content of the interview. Make sure your opinions and behavior neither add to nor subtract from the research intention of any items on the form.

### **Clarify the Nature of the Research Setting**

The DPPOS consent form, which all participants (or the appropriate surrogates) have signed, informs participants that they are in a research study and that it will not provide medical care. Whether you are conducting the interview in the home or in an interview room at the hospital, the participant should continue to be reminded that, the study is not part of their medical care. Interviews (and interviewers) should be consistent with this at all times and the participant should be aware that you are an interviewer not their nurse, doctor/physician, caregiver, helper, or advisor. If participants have a concern about their health, recommend that they see their primary care physician.

Remember that participants in DPPOS join and remain in the study voluntarily. As is stated in the consent form, there is no direct benefit to participation in the study. Aside from the reimbursement for participation, participants importantly contribute to the content of scientific knowledge.

## Interviewer Preparation

Studies have shown that a participant often remembers more about the interviewer and how the interview was conducted than about the topics covered during the interview. This finding emphasizes important aspects of interviewing. For successful interviewing, you should have broad knowledge of the research project interview task as well as of the forms and how to fill them out. Your knowledge base should include the following:

- *Understand your role.* An interviewer must be an understanding person capable of accepting what the participant says without showing reactions of either approval or disapproval; the participant must feel that their ideas are important, and that there are no right or wrong answers. An interviewer must not influence the participant by anything they say or do. An interviewer must help the participant feel that the interview is an important contribution to research.
- *Understand the nature of research interviewing.* An interview is a social interaction designed to exchange information between a questioner and a participant. The quality of the information exchanged depends upon the skill of the interviewer in handling that relationship.
- *Understand the scope of research interviewing.* The research project interviewer collects data that will answer research.
- *Understand the objective of the research interview.* The research interview contains elements that separate it from other kinds of interviewing. Strictly speaking, the research interview is a relationship in which the interviewer has the practical, utilitarian goal of data collection. Research project interviewers must combine the utilitarian objective with the more social objective of participant retention.
- *Understand that the interview is partly a retention tool.* The retention objective is an important one, and rapport building and social interaction should be a part of every interview. But it is also important that the interview not drift into lengthy conversation. Conversation of a general nature for the purpose of rapport building should be confined to a few minutes at the beginning and the end of participant visits or phone calls.
- *Understand the significance of research interviewing.* The research project is dependent upon the reliability and validity of the data collected by its interviewers. Bias and lack of standardization in interviewing can compromise data. The interviewer reduces the chance of bias by presenting neutral reactions to all answers and by maintaining a brisk, regular pace of question delivery. Regardless of how carefully worded the questions and how neutrally presented, research interviews are subject to bias from two sources: interviewer delivery and participant responses. It is the interviewer's job to minimize bias from either source.
- *Understand sources of potential bias.* Interviewers can introduce bias into survey results by interpreting answers, favoring one answer over another, confusing self-report (subjective) questions with objective assessment, treating some questions as sensitive, reacting to liked or disliked participant characteristics, or using slanted probes or positive or negative filler words. To avoid these potential sources of bias, interviewers must perfect standard interviewing, neutral delivery and neutral response.
- *Read Examiner Scripts verbatim.* Use the scripted parts of the interview as they are written. Discuss with your supervisor the content and flow of recommended remarks, especially when in

doubt about appropriate procedures to follow in unusual situations. It is important to communicate to the supervisor any specific problems, questions, and suggestions for improvement.

- *Know the forms thoroughly.* Follow all instructions and scripts contained on the form itself and in the operations manual. Following or not following the instructions, scripts, or recommended remarks makes the difference between consistent and inconsistent data.

### **Conditions of Interviewing**

The conditions of the interview are a prominent part of the experience and quality of data collected.

- Be on time. Be sure to identify yourself and be ready to show identification.
- The preferred seating arrangement for most of the procedures will be around a table. If this is not possible, sit oneself across from the participant in a chair, using a clipboard for recording information. Always carry a clipboard with you for writing in case there is no table convenient on which to write.
- Both you and the participant should be seated comfortably in a quiet, private location. Try to be in a position that will:
  - Allow you to have easy eye contact with the participant.
  - Enable you to be heard without raising your voice (you may need to ask the participant to use their hearing aid or use a hearing assistance device if possible).
  - Avoid light glaring in either the participant's or your eyes.
  - Permit you to write unobtrusively.
- It is important that the participant be the only respondent during the cognitive interview. Discourage distractions from other people by letting the participant know the interview will go much faster if there are no interruptions.
  - The spouse/partner, friends, or relatives should not be present during the interview, because their presence may influence the participant's responses to questions.
  - If someone is with the participant and is reluctant to leave, explain the necessity of privacy for study purposes and be prepared to suggest places where this individual can wait comfortably. You might say, "This will take about 20 minutes; the coffee shop is located down the hall", etc.
- Strive to achieve the following conditions if the informant is present but the current questions are not being asked of an informant:
  - It is possible that an over-protective relative or a shy participant will not permit a private interview. In these situations, you must focus on the target participant and attempt to minimize any participation from the other person.
  - Be pointed in directing your questions to the participant and in maintaining steady eye contact with the participant.

### **Confidentiality**

Participants must be assured of confidentiality and it is critical that confidentiality be maintained throughout the study. As noted by Westat (1987): "An interviewer must often ask questions that one

would not think of asking even a close friend. Most people, however, are willing to answer such questions when they are asked in an interview. They are willing to give information because they trust that it will be used only for serious purposes." Your protection of all information about participants gained during the conduct of research is therefore essential. This means to protect not only the information you get in direct response to the questions you ask in an interview, but also the information you gather through incidental observations of the participant.

- It is important that care be taken in maintaining confidentiality of completed questionnaires while they are in your possession. Always make sure that questionnaires are not left where non-research staff can view them. You must safeguard the completed questionnaires by not leaving them unattended.
- Names of participants are not on the data forms, only their study ID number.
- It is your duty to keep the promise of confidentiality. Never divulge names, tell facts about or reveal the opinions of anyone you interview. Information collected or seen during an interview can be shared only with the research team, whose members are under the same ethical or moral obligation as you are to the participants interviewed. As you may know, persons who participate in research studies have rights to privacy that are protected by federal law. Maintaining confidentiality of data is not just a philosophical issue for an interviewer. It means that an interviewer must be aware of the importance of protecting the confidences of the study participants on a day-to-day basis. For example, an interviewer's comment to a friend outside of the research team about a particular participant or about a participant's response is a breach of confidentiality and is considered unprofessional and unethical conduct.

### **Auditory-Limitations in Hearing**

A gradual hearing loss begins about age 20. As age increases, sharpness and accuracy of hearing often diminish. This type of hearing loss may make a person misunderstand words, which is often interpreted as confusion. Inability to hear well, i.e. noise from other sources (people talking, dishwasher or TV on, etc.) may make it difficult for a hearing impaired person. In the English language, consonants are more important in the identification of words than vowels, i.e. they are slightly softer in sound. Unfortunately, some consonants, e.g. s,z,t, f and g, are some of the higher frequency sounds that are lost when hearing impairment occurs.

- Hearing limitations may be detected by the presence of a hearing aid or by behavioral cues, such as the appearance of inattentiveness or a strained facial expression, particularly with listening. People with hearing limitations may lean forward toward the interviewer with their "good" sides, tilt their heads, or cup their hands behind their ears. Others with hearing problems may show none of these behavioral signs but may answer questions inappropriately or frequently ask questions to be repeated.
- People with hearing limitations may tire easily or show annoyance because of pain or auditory blurring when the interviewer speaks too loudly. It requires a great deal of effort for them to listen and to sort and file sounds into meaningful thoughts, especially when the conversation and the interviewer are both strange to them. People with hearing impairments may tire and

give up, so be patient. Here are some tips on communicating with a person who has a hearing impairment:

- Speak slightly louder than normal and, if you can, lower the pitch of your voice. Remember that shouting will not make your message any clearer and may sometimes distort it.
- Speak a little slower than normal rate without making it stilted or unnatural.
- Avoid chewing, eating or covering your mouth with your hands when speaking to an older person who is hearing impaired.
- The best distance when speaking to an elderly person with a hearing impairment is from 3 to 6 feet.
- Facial expression, gesture, lip and body movements all give cues to the person with the hearing impairment. Therefore, good lighting on the face of the speaker is important.
- Wait until you are visible to the older person before speaking, and face the participant when you speak. If possible, arrange the environment so that the speaker's face and body can be seen easily.
- Communication with older persons who have hearing impairments is much more difficult when there are other noises in the environment.
- Never speak directly into the person's ear. This may distort your message and further hide visual cues.
- If the person with the hearing impairment does not appear to understand what is being said, rephrase the statement in short, simple sentences. Of course, you may not rephrase interview questions - simply repeat an interview question slowly while maintaining eye contact with the participant.
- Whenever possible, give the person with the hearing impairment a clue to the topic of conversation, such as "Now we're going to talk about..."
- Some consonants are louder or more visible than others. For example 'p' is easier to see on the lips than 'k'. Therefore, some words or parts of conversations may be more easily heard or understood than others.
- Individuals with hearing impairments may take longer to respond; give them time.
- Do not make sudden movements that could startle the participant who gets no pre-warning from sound.

### **Limitations on Vision**

Between the ages of 40-45, certain changes begin in the eyes. The lens and the muscle begin to stiffen. Many people who never wore glasses before need them to read. With advancing age, other changes take place in the eyes which can often make the environment seen faded; and cause light refraction and a loss of some visual detail. Some results of these changes can be that more light is required to see; yet glaring light causes discomfort and, in the case of night driving, are hazardous.

- Difficulties in vision may be identified by the presence of thick or dark glasses, a cloudy film over the eyes, or other discoloration of the eyes. However, some visual problems have no obvious signs. In these cases, you may be able to infer visual limitations by the manner of the participant's mobility and balance.

- People with visual loss depend upon immediate sounds and tactile sensations to maintain their sense of security. They may be fearful, distrusting, and awkward in movement.
- Some of the behavioral manifestations of visual loss include the following:
- A handshake may be missed because the offered hand is not seen;
- A participant may be unable to read cue cards, your identification, etc.;
- People with visual impairments may be unable to recognize other people. They may also be unable to distinguish an object from its background (objects may be knocked over or dropped); and
- Individuals with visual impairments may be unwilling or unable to move about freely because of inability to see objects in their path;
- Individuals with impaired vision may wear mismatched clothing, apply makeup inappropriately, wear clothing that is stained if they are not aware of them, or appear to be inadequate housekeepers as crumbs, spills and dirt may not be observed.

### **Limitations in Language Function**

Limitations in language function may have many causes. People with limitations in language function probably know what they want to say, but are unable to form words. Do not assume that such people lack intelligence. People with limitations in language are especially sensitive to the attitude and moods of others and may become irritated over minor incidents. They are often frustrated about their inability to communicate. There may be marked loss of self-confidence and self-worth.

- Some tips on handling limitations in language functions include the following:
  - Give the participant time to answer without pressure and be attentive.
  - Be careful not to put words in the participant's mouth because he/she appears to be having difficulty expressing him/herself. Instead, give time and encouragement.

### **Limitations in Mobility**

If a person is limited in mobility or has experienced paralysis, you should be careful about the physical arrangements of the exam - seating, lighting, and availability of a table - so as to minimize the need for the older person to move or to perform on her affected side. In such circumstances, be considerate of the participant's needs.

- When working with people with physical impairments, remember that:
  - They may not be able to sit for long and may have to move around.
  - They may tire more easily and you may have to allow them to rest or reschedule to complete the interview.

### **Problems in Conducting the Interview**

In addition to the problems discussed earlier, you may encounter unusual situations in trying to complete the exam and interview. Some examples are discussed below.

- *Participant cannot do entire interview in one sitting.* Always try to complete the exam at one sitting. However, if it becomes obvious during the interview that the participant cannot complete it all because of physical limitations or mental fatigue, another visit should be scheduled within a few days.
- *Participant requests another person during the exam.* Explain to the participant that the interview may go faster with just him/her. However, if the participant insists that someone else be present, accept the request.
- *Participant is very talkative.* Frequently you will encounter a participant who wants to talk at much length about themselves or in a social manner, or a participant who is not able to or willing to focus on the task at hand. While being accepting of the person and their needs, do not hesitate to interrupt the participant gently but firmly, and saying something like, "I don't want to take up too much of your time, so let's continue with the task."
  - It also helps to lose eye contact with the participant, look down at the interview instrument, then look up and say, "Perhaps you can tell me more about that when we are finished. Now I'd like to ask you...," "Isn't that interesting. Now let me ask you this...," as a last resort, "Excuse me, but let's get back to the task."
- *Participant becomes upset.* Very occasionally a participant will become upset or cry during the interview. Participants who have recently lost loved ones, especially to one of these illnesses, may become upset with some questions.
  - If this happens, remain calm but not distant or cold; let the emotion run its course. Have tissues available. Often participants who have experienced losses express strong motivation to continue with the project to contribute to the disease prevention effort.

## **2. FIELD CENTER PROCEDURES**

A trained examiner administers the cognitive function tests in a fixed order, one right after the other, during a single session in a quiet room. The tests are administered following the instructions printed on the Neurocognitive Assessment paper forms. Test results are tabulated by the interviewer after the participant has completed the tests and left the room.

The order of test administration is as follows: (1) Six Item Screener, (2) Spanish English Verbal Learning Test, (3) Word Fluency Test, and (4) Digit Symbol Substitution Test.

The testing environment and examiner behavior should be geared toward optimizing the participant's performance on each of the cognitive measures. General testing procedures are detailed below.

Always inquire if the participant uses reading glasses or wears a hearing aid. If so, these items should be worn during testing.

The testing room must have a table with sufficient work space and appropriate lighting for the participant to comfortably complete the Digit Symbol Substitution Test.

A good quality stopwatch is necessary to time components of the cognitive function exam. 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).

Timing should always be as discrete as possible to avoid producing anxiety and affecting test results.

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.

Although time limits are set for some tests, the participant should not be told of any time limit on any measure, unless they ask.

Participants are often curious as to how well they did. Although scoring does not take place during testing, the interviewer should reassure each participant who asks that he/she did as well as others who have taken the tests. Do not indicate to the participant whether specific responses are correct or incorrect.

Most participants will feel challenged, however, some may feel insecure and others possibly hostile. It is important for the interviewer's attitude to be friendly, non-threatening, reassuring and supportive throughout the testing.

Examiners should be sensitive to provide positive reinforcement (e.g., "you're doing fine") after each test if appropriate.

### **2.1 Six-item Screener (Part A)**

The six-item screener, derived from the Mini-Mental Status Examination, is a short measure of global mental status. Following the script on the paper form, the examiner briefly explains the purpose of the cognitive function portion of the DPPOS examination and then proceeds with the instructions for the six-item screener.

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

**Spanish Script:** *"En la siguiente parte del examen le voy a hacer algunas preguntas y le voy a dar un par de actividades cortas que requerirán de su memoria y concentración. Primero, le voy a hacer algunas preguntas que requieren del uso de su memoria. Voy a decir tres palabras. Por favor, espere hasta que yo diga esas tres palabras. Después de eso, repítalas usted. Recuerde cuáles son, porque le voy a pedir que me las nombre de nuevo en unos minutos. Por favor, repítame estas palabras: AZUL – PERA – 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”** **“Repita las tres palabras otra vez”** and score according to the response to this request.

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 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/Disability," or if the participant refuses to complete the task mark "Not Attempted/Refusal."

If the participant fails to repeat all three words correctly after three attempts, items 5, 6, and 7 will not be testable and should be marked as "Not Attempted/Disability." In the event that a participant refuses to complete the task (i.e., item 1 is marked as Not Attempted/Refusal), then items 5, 6, and 7 should be marked as "Not Attempted/Refusal."

Record the number of presentations necessary for the participant to repeat all three words correctly.

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

Orientation question #1: **“What year is this?”**  
**“¿En qué año estamos?”**

Prompts:

If the participant gives you an off or ambiguous response repeat the question. For example, if the participant responds with the name of the test site, say **“I will repeat the question. What year is this?”**

If the date of testing is within one week of a change of year and the subject’s response is incorrect, say, **“Are you sure?”** **¿Está seguro/a?**

Orientation question #2: **“What month is this?”**  
**“¿En qué mes estamos?”**

Prompts:

If there is no response after 10 seconds, repeat the question.

If there is no response after repeating the question, wait 10 seconds and prompt with a list of relevant names without penalty (**"Is it January, February, March...?"**). **"¿Es Enero, Febrero, Marzo...?"**

If the date of testing is within one week of a change of month and the subject's response is incorrect, say, **"Are you sure?"** **¿Está seguro(a)?**

Orientation question #3: **"What is the day of the week?"**  
**"¿Qué día de la semana es hoy?"**

Prompts:

If the participant responds with a date instead of the day of the week, repeat the question.

If there is no response after 10 seconds, prompt with a list of relevant names without penalty. (**"Is it Monday, Tuesday, Wednesday..."**, **"Es hoy Lunes, Martes, Miercoles..."**)

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 (~ 10 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?"**  
**Ahora, ¿cuáles fueron esas tres palabras que le pedí que recordara?**

Record the appropriate response next to each item.

The words may be repeated in any order.

Recalled words are considered correct only in the language in which the original words were provided.

### **2.1.1 Six-item Screener (Scoring and Discontinuation)**

Items 1-6 on the six-item screener are scored as correct, incorrect, not attempted/disability, 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 a reasonable amount of time check, "Not Attempted/Refusal."

If an item is not attempted due to a physical impairment (such as hearing loss) check "Not Attempted/Disability" for each item affected. In this instance, continue on to the next question without delay.

Only exact responses are correct.

## **2.2 Spanish English Verbal Learning Test (Part B)**

The Spanish English Verbal Learning Test (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 are requested again following 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.

**English Script: "Next, I am going to read a list of words to you. 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. You will 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. Are you ready?"**

**Spanish Script: *A continuación, voy a leer una lista de palabras. Quiero que escuche cuidadosamente y que trate de recordar las palabras a medida que las leo. Cuando me detenga, me gustaría que recordara tantas de las palabras como usted pueda. Usted no podrá acordarse de todas las palabras, así que simplemente haga lo más que pueda. No tiene que recordar las palabras en el mismo orden que yo las leo. Listo (a)?"***

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

Script: **"Now tell me all of the words you can remember."**  
***"Ahora dígame todas las palabras que usted pueda recordar."***

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

To record the words recalled, write out the words as they are being recalled in the appropriate column for each trial. (Words do not have to be recalled in the order in which they were read.)

Recalled words are considered correct only when stated in the language in which the examiner provided the words. If the participant begins to produce the recalled word in another language say **"Please tell me the word in English."** ***"Por favor dígame la palabra en español ."***

Once the participant has produced as many words as he/she appears able to recall or after 15 seconds , with no response provide one prompt, **"Anything else?"**, in Spanish **"¿Alguna otra palabra?"** for additional words before going on to Trial 2.

Do not allow more than 60 seconds for recall for any trial.

The word list is repeated 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."**

**Spanish script: "Voy a leerle la lista de palabras de nuevo. Quiero que trate de recordar tantas de las palabras como pueda, incluyendo aquellas que recordó antes. Cuando me detenga, quiero que me diga tantas palabras como usted pueda recordar"**

Present the 15-item word list.

Script: **"Now tell me all of the words you can remember."**  
***"Ahora dígame todas las palabras que usted pueda recordar."***

Discretely start the stopwatch.

To record the words recalled, write out the words as they are being recalled in the appropriate column for trial 2. (Words do not have to be recalled in the order in which they were read.)

Once the participant has produced as many words as he/she appears able to recall or after 15 seconds with no response, provide one prompt, **"Anything else?"**, in Spanish **"¿Alguna otra palabra?"** for additional words 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 list again. Listen carefully and when I finish tell me as many of the words as you can remember."**

**Spanish script: "Voy a leer las mismas lista de palabras una vez más. Escuche cuidadosamente y cuando yo termine dígame tantas de las palabras como usted pueda recordar."**

Present the word list.

Script: **"Now tell me all of the words you can remember."**  
***"Ahora dígame todas las palabras que usted pueda recordar."***

Discretely start the stopwatch.

To record the words recalled, write out the words as they are being recalled in the appropriate column for trial 3. (Words do not have to be recalled in the order in which they were read.)

Once the participant has produced as many words as he/she appears able to recall or after 15 seconds with no response, provide one prompt, **“Anything else?”** , in Spanish **“¿Alguna otra palabra?”** 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 words 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.**

**Spanish script: “Ahora, voy a leer una lista diferente de palabras. Esta vez, quiero que repita cada palabra en voz alta después de que yo la lea.”**

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, that is the list that I read to you three times."**

**Spanish script: “Ahora, quiero que me diga tantas de las palabras de la primera lista que yo le leí como usted pueda recordar, la que leí tres veces.”**

Discretely start the stopwatch.

Do not repeat the first list.

If the participant says that he they cannot remember any of the words on a given trial, encourage him or her by saying, **“Just give it a try”** or **“Take a moment to see if any of the words come to mind”** **“Trate a ver si puede”, “Tome un momento a ver si alguna de las palabras le vienen a la mente.”**

To record the words recalled, write out the words as they are being recalled in the appropriate column for trial 4. (Words do not have to be recalled in the order in which they were read.)

Once the participant has produced as many words as he/she can recall, provide one prompt for additional items, say **“Anything else?”** **“¿Alguna otra palabra?”** or **“See if you can think of anymore”, “Trate a ver si puede pensar en otra mas.”**

Do not allow more than 60 seconds for recall.

### **2.2.1 Spanish English Verbal Learning Test (Scoring and Discontinuation)**

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

#### Types of responses

##### Correct

Recalled words are considered correct only when stated in the language in which the words were provided by the examiner.

##### Intrusions

A response is classified as an intrusion error when the response is not on the current target list.

##### Repetitions

A repetition is scored each time any response (whether a target word or intrusion) is repeated on the same trial. If the participant appeared to be repeating responses as a way of self-cueing, do not score it as a repetition error.

In the column "Resp Type" short for 'Response Type' record a "C" for correct words, record an "I" for intrusions or record an "R" for repetitions next to each word recalled.

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 functioning. In this task, participants are asked to produce as many words as possible that begin with the letter F (letter P for Spanish speakers) within a time limit of 60 seconds for each letter, avoiding proper nouns, variations, plurals, and repetitions.

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. Leave out names of people and names of places. So, if I were to say "T," you could say words like 'table,' 'take,' or 'turtle' but could not say words like 'Thomas,' or 'Texas'.**

***Spanish Script: "En la siguiente actividad, voy a decir una letra. Luego, quiero que me diga tantas palabras, que sean diferentes, como usted pueda imaginarse y que comiencen con esa letra. Excluya los nombres de personas y los nombres de lugares. Por tanto, si yo dijera "T,"***

*usted puede decir palabras como 'tabla', 'tomar' o 'tortuga' pero no podría decir palabras como 'Tomás', o 'Texas,'*

Pause.

**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?"**

**Spanish script: "Tampoco use la misma palabra otra vez con diferente final. Por ejemplo, si usted dice 'tomar', entonces no puede decir 'tomaron' o 'tomando'. Todas ellas se considerarían como la misma palabra."**

Pause.

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

**Spanish script: "Dígame tantas palabras como pueda que comiencen con la letra P. Yo le diré cuándo puede detenerse. Listo, empiece."**

Discretely start the stopwatch when the participant provides the initial response and record the participant's responses verbatim.

If after approximately 5 seconds, the participant gives no words, then begin stopwatch and repeat the basic instructions, say,

**"Remember please tell me as many words as you can that begin with the letter F."**

***"Recuerde, dígame tantas palabras como pueda que comiencen con la letra P."***

No extension on the time limit is made in the event that the instructions are repeated.

If at any time during the 60 seconds the participant cannot think of any more words, wait quietly for 10 seconds. After 10 seconds of silence prompt for more words, say:

**"Can you think of any other words that that begin with the letter F?"**

***"¿Puede pensar en otras palabras que comiencen con la letra P?"***

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; just go on."** ***"Esta bien, siga."***

The examiner may clarify the instructions only when the participant has clearly misunderstood the instructions and is only providing inadmissible words such as only stating proper names or only listing numbers.

If participant repeatedly provides incorrect responses, they may be re-instructed not to provide proper nouns, variations (e.g., run, runs, running), or words starting with an incorrect letter. Each of these errors may be corrected (queried) only **once within** each 60 sec. trial. You can say,

#### Queries for errors

If they provide proper noun: **“Remember, no names of places (people).”**  
**“Recuerde, no diga nombres de personas (lugares).”**

If they provide variation of a word: **“Remember, not the same word with a different ending.”**  
**“Recuerde, no use la misma palabra con diferente final.”**

If they provide a word starting with a different letter: **“Remember, tell me words that begin with the letter F.”**  
**“Recuerde, dígame palabras que comiencen con la letra P.”**

If the participant repeats a previous word, do not interrupt; simply circle the error.

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

Query words that can be both proper names and regular nouns at the end of the 60 sec. interval. For example, if the participant says “frank”, at the end of the 60 sec. interval you should ask: **“What did you mean when you said ‘frank’?”** *Qué quiso decir cuando dijo\_\_?*

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 introduces the next task, category fluency.

Category fluency is a measure of verbal fluency. It assesses ability to generate exemplars from a category provided by the examiner. Fluency in the animal category is assessed. Participants are allowed 60 seconds to generate names of animals.

Say to the participant,

**“I want to see how many different animals you can name. Any animals will do; they can be from the farm, the jungle, the ocean or house pets. They can begin with any letter. Go as quickly as you can. Ready, begin!”**

**Spanish script: “Quiero ver cuantos animales diferentes usted puede nombrar. Cualquier animal esta bien; puede ser de la finca, de la selva, del océano u animales domésticos. Los nombre pueden comenzar con cualquier letra. Vaya lo mas rápido posible. Empiece.”**

Discretely start the stopwatch when the participant provides the initial response and record the participant's responses verbatim.

If after approximately 5 seconds, the participant gives no response, then begin stopwatch and repeat the basic instructions, say, “ **Remember, please tell me as many animals as you can. They can begin with any letter.**”

***“Recuerde, dígame cuantos animals com ousted pueda. Pueden comenzar con cualquier letra.”***

If at any time during the 60 seconds the participant cannot think of any more words, wait quietly for 10 seconds. After 10 seconds of silence prompt for more words, say:

**“Can you think of any other animals?”**

***“¿Puede pensar en otros animales?”***

If they provide a word beginning with the letter F, say “**Remember , give me names of animals.**”

***“Recuerde, dígame nombres de animals.”***

After 60 seconds has passed, the examiner stops the test.

### **2.3.1 Word Fluency Test (Scoring and Discontinuation)**

After the participant has left the room, the examiner must proof all the responses for admissibility. The examiner should finish writing out any words that were not completely written out during the exam. Clarify any words that may have been unclear during the time the test was given. If unable to spell the word, write it out phonetically. Check any ambiguous words in the dictionary (only after the participant has left the room).

If the participant is **not literate** and reports that they are unable to do the test, it should be scored as impairment. However, do not assume that an individual with no or few years of formal education cannot do the task; in fact, many people who cannot read or write attempt this task.

Some participants who cannot read or write will refuse to attempt the test, but you will be unable to determine if they would be able to produce words if they were to attempt the task. In this case, it should be scored as “refused”.

The total score for each trial is the number of correct words produced, and does not include repetitions, perseverations, or other incorrect responses (as defined below).

Repetitions: A repetition is scored when a word is repeated within a 60-second trial (e.g., friend, fame, fantastic, *friend*).

Perseverations: A perseveration is scored when the participant provides a response that is incorrect, but that would have been acceptable for a previous trial (e.g., providing “F” words during “ANIMAL” fluency). Perseverations are scored for the fluency trial (i.e., “F” words) if the participant perseverates on the stimuli used (i.e. “T” words) in the example.

Incorrect: Responses that are incorrect include proper nouns and any other response that is incorrect that is not a repetition or perseveration.

### Letter Fluency

Circle any inadmissible words, i.e., proper nouns, variations (e.g., change in suffix such as "ed"), incorrect words and repetitions.

Record the number of admissible words, repetitions and perseverations 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 (P for Spanish) but actually begin with another letter) are inadmissible.

The instructions include a specific prohibition against giving different forms of the same words.

In scoring this measure, it is useful to keep in mind the purpose of the test: It is to measure verbal fluency. Hence, if two words seem similar, but they are clearly separate words, give credit for both. If two words seem similar because they are a simple derivation of the word, or the same word with an added suffix (e.g., -s, -ed, -ing, -ly), the second word should be considered a repetition.

Slang terms are admissible if in general use.

Days of the week are *not acceptable* in English or in Spanish (e.g., Friday, viernes), because they are proper nouns.

In the case that the participant begins to give a numerical series (e.g., 51, 52, 53, 54...), only the first number is counted as correct. Numbers that are not a series (e.g., 4, 5, 40, 50) are counted as correct.

Foreign words (e.g., passé, lasagna, pasta, Lebensraum) are admissible if they can be considered part of the English lexicon, the criterion being their listing in a Standard English dictionary.

Words which are capitalized but are not specifically proper nouns will be counted as correct: Fauve, Christian, Lutheran, etc.

Cases where the examiner is unclear about scoring should be referred to the Principal Site 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.

### Category Fluency

Score as you would score Letter Fluency, including total correct, incorrect, perseverations, and repetitions.

Perseverations can include incorrect responses that start with the letter F. For example, for animal fluency “fox” would be scored as a correct response; however, “funny” would be scored as a perseveration (not an incorrect response).

#### **Specific responses for *animals*:**

<b><u>YES</u></b>	<b><u>NO</u></b>
dinosaurs	mythical or imaginary beasts
fish	unicorn
birds	Pegasus, etc.
bestia* (Spanish)	Teddy bear

\* accept if referring to a mare, not if referring to a beast

- Listing species (e.g., poodle, cocker spaniel, Springer spaniel, Doberman) is acceptable.
- In Spanish, if participant gives the male and female of an animal only count one. ex. gallo, gallina.

## **2.4 Digit Symbol Substitution Test (Part D)**

The Digit Symbol Substitution Test (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:** "This last task is the digit-symbol task. Look at these boxes. 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."

**Spanish script:** *"Esta última actividad es la actividad de dígitos-símbolos. Mire estas casillas. Note que cada casilla tiene un número en la parte de arriba y una marca especial en la parte de abajo. Cada número tiene su propia marca."*

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."

**Spanish script:** *"Ahora, mire aquí abajo adonde los cuadrados tienen números en la parte de arriba, pero los cuadrados de abajo están vacíos."*

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."  
*"Quiero que coloque la marca que debe ir en cada uno de los cuadrados vacíos, así."*

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. So I put it in this square, like this."  
*Aquí hay un 2; el 2 tiene esta marca. Entonces, lo coloco en este cuadrado vacío, así*

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

**Script:** "Here is a 1; the 1 has this mark."  
*Aquí hay un 1; el 1 tiene esta marca.*

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

**Script:** "So I put it in this square."  
*Entonces, lo coloco en este cuadrado.*

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

**Script:** "This number is 3; the 3 has this mark."  
*Este número es el 3; el 3 tiene esta marca.*

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

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

***Entonces, lo coloco en este cuadrado***

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."**

***Ahora llene usted los cuadrados hasta que llegue a esta línea gruesa.***

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:

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

***Sí, ya sabe cómo hacerlo.***

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."**

***Cuando yo le diga que comience, haga el resto.***

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."**

***Spanish Script: "Comience aquí y llene tantos cuadrados que usted pueda, uno detrás del otro sin saltarse ninguno. Siga haciéndolo hasta que le diga que pare. Hágalo tan rápido como pueda sin cometer ningún error."***

Sweep across the first row with your finger and say,

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

***"Cuando termine esta línea, siga con esta otra."***

And point to the first item in row 2.

Script: **"Ready? Go ahead."**  
***¿Listo? Comience."***

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."**  
***Hágalos en orden. No salte ninguno.***

Point to the first item omitted and say:

Script: **"Do this one next."**  
***Después, haga éste.***

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

Script: **"Please go on to the next line."**  
***Cuando termine esta línea, siga con esta otra.***

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. That completes this set of tasks."**  
***"Deténgase. Así está bien, gracias. Eso completa este conjunto de actividades."***

#### **2.4.1 Digit Symbol Substitution Test (Scoring and Discontinuation)**

After the participant has left the room, the examiner scores the DSST. Using the DSST 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") 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 DSST 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 Cognitive Assessments Questionnaire**

Part A. Participation Identification- complete this before the visit.

Cognitive Assessments Questionnaire forms are completed after the participant has finished the cognitive tests and left the exam area.

Record a three-letter- initials identification code of the interviewer completing this form corresponding to the interviewers first, middle and last name. If an interviewer does not have a middle name, write in an "X". For example, John Smith's identification code would be "JXS".

Part B. Cognitive Assessment Summary

The Six Item Screener, SEVLT (Part B), Word Fluency Test (Part C), and Digit Symbol Substitution Test (Part D) are all scored after the participant has left the exam area.

Items 8 (a-d) SEVLT-Record the number of correct words recalled from the SEVLT form for each of the three learning trials (Trials 1-3) and the recall trial (Trial 4). Record the number of intrusions and repetitions for each trial. Refer to section 2.2.1 for scoring instructions.

Items 9 (a-b) Word fluency- Record the number of acceptable words produced for the letter F (letter P for Spanish Speakers) and Animal Category. Record the total number of perseverations and total repetitions for both letter and category fluency. Refer to section 2.3.1 for detailed scoring instructions.

Item 10: Apply the DSST scoring template to the response form and record the number of correct symbols. Refer to section 2.4.1 for detailed scoring instructions.

If any test scores are permanently missing because part of the battery was skipped or discontinued, enter "=" in those fields.

Section C. General Questions

Item 1. Record the language in which tests were administered

Item 2 (a-c): Record whether cognitive tests parts B, C, or D were discontinued. If none was discontinued, the Neurocognitive Summary Form is complete.

Note which tests (Item 2, a-c) and the reason(s) as 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 DPPOS examination, examiners will be trained centrally to a common level of proficiency in the administration and scoring of the neurocognitive measures. Following central training, examiners will obtain approval from the field center lead examiner or study coordinator and submit three audio-taped neurocognitive assessments along with copies of the associated paper protocols to the Principal Site at Columbia University for review. Certification assessments should not be performed on DPPOS participants.

Examiner certification for the neurocognitive portion of the DPPOS exam is achieved by the successful administration and scoring of the three certification assessments reviewed and approved by the Principal Site.

The field center lead examiner or study coordinator 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-taped neurocognitive assessments for review and approval by the Principal Site for certification.

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

Recertification will be performed annually and requires the successful administration and scoring of one audio-taped neurocognitive examination reviewed and approved by the Principal Site. An actual participant assessment may be submitted for recertification purposes.

#### **3.2 Quality Assurance**

Several procedures are in place to monitor data quality. With participant approval, all assessments are routinely audio-taped for quality control.

During the first six months of the study, two audio-taped exams and associated paper protocols for each examiner will be review by the Principal Site to ensure appropriate pacing and technique, adherence to protocol, and accuracy of recorded responses and scoring. Copies of at least 10% of the paper protocols will be sent to the Principal site for double scoring.

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-taped exam and associated paper protocol for each examiner will be reviewed for accuracy and adherence to protocol by the Principal Site.

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

The site coordinators will conduct quarterly field observations to assess examiner performance and ensure an optimal testing environment.

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

### **3.3 General Training Guidelines**

The site coordinators/lead examiners will train new examiners with strict adherence to the following guidelines:

#### 1. Pre-certification, Training and Observation

a. Coordinator/lead examiner will email Principal Site (Columbia University) and interviewer an acknowledgement that the interviewer's training has begun. The email will include what neurocognitive tests/forms are included in the certification.

b. Interviewer reviews updated forms & manual (check with Study Coordinator that you have the most updated manual).

c. Coordinator/lead examiner and interviewer will review forms/manual and answer any questions.

d. With manual in hand, the interviewer will observe the project coordinator/lead examiner or a coworker administer the test/form either in the field or in the office on a coworker. The interviewer will ask the project coordinator any questions that arise as a result.

e. With manual in hand, the interviewer will practice administering tests/forms to a DPPOS staff member and co-worker at least twice.

f. Coordinator/lead examiner will set up mock interviews where multiple scenarios are presented.

g. Questions, observations will be reviewed with coordinator and feedback will be provided. This will continue until procedures are clear.

## 2. Certification

a. Coordinator/lead examiner will observe interviewer administering tests/forms to a participant at least twice.

b. If additional training is needed, this will be documented in an email to Principal Site in addition to new certification date.

c. Principal Site will be notified via email that certification is complete.

## Post-certification

a. Observation in field will be repeated regularly with feedback and clarification from Coordinator/lead examiner. If additional training is needed as a result of observations in the field, this will be documented in an email to Principal Site in addition to new certification date.