	Title:	Neuropsychological Battery DCS		
	Version Date:	2015-JUN-30	Document Number:	SOP_DCS_0019
	Effective Date:	2015-JUL-15		
Data Collection Site (DCS)	Version:	3.1	Number of Pages:	9

1.0 Purpose:

The purpose of this document is to describe the standardized procedure for administering the four tasks of the Neuropsychological Battery which include the Event-based Prospective Memory Test (PMT), Stroop Neurological Screening Test, Controlled Oral Word Association Test (FAS), and Choice Reaction Time Test (CRT).

2.0 Scope:

DCS staff will use this document when administering the Neuropsychological Battery to participants.

3.0 Responsibilities:

DCS staff are responsible for performing the procedures as described in the current and approved version of the standard operating procedure.

4.0 Related Documents:

- Neuropsychological Battery Questionnaire
- **SOP_DCS_0020** - Hearing SOP

5.0 Definitions:

- **Intention to Perform:** the degree to which the signal (i.e., the alarm going off) elicits a self-initiated response from the participant.
- **Accuracy of Response:** the degree to which the target action is performed as originally instructed. It is scored based on the correspondence between object (i.e., what bill denominations to select) and participant (i.e., which person gets which denomination).
- **Need of Reminders:** the number of reminders (up to three) needed by the participant to initiate or complete the task.

6.0 Equipment:

- External headset with a microphone

7.0 Supplies:

- Envelope containing money
- Oven timer
- Event-based PMT reference sheet
- Stroop stimulus cards (set of 3) – **DO NOT LAMINATE**

8.0 Procedure Steps:

Contraindications:

- Participant cannot hear the timer or pick up the envelope (event-based PMT).
- Participant has a severe or complete visual impairment (event-based PMT, Stroop, Choice Reaction Time).

Administer the tasks in the order in which they appear in this document. **Note that you will be required to move back and forth between the different modules described in this SOP.** Precise adherence to time limits and standardized instructions is critical.

Pausing a Module:

There are many places throughout this SOP which direct the user to pause a module. To pause a module in Onyx:

Step 1: Click on **Administration**.

Step 2: Click **Pause**.

Step 3: Enter your password and choose the reason - *Interviewers Decision* if required.


Step 4: Enter the comment *paused*.

Step 5: Click **Continue**.

Recording a Participant:

Anytime you record a participants response in Onyx follow the steps as outlined below.

Step 1: Click on the "O" radial button before the timer.

Step 2: Click on the "  **Record**" button to begin recording the participant (this will also start the timer). Watch the computer monitor to ensure the participant's voice is being picked up on the recording. You will see the sound waves fluctuating as the participant talks.

Step 3: Watch the time and inform the participant when the time has elapsed.

NOTE: A beep will sound in the participant's headphones.

Step 4: Press the "  **Stop**" button once completed.

Timer instructions: The timer will count up. The timer should not be reset or paused. Do not stop the recording until the prescribed amount of time for the test has passed.

DO NOT stop and re-record a participant's response unless the participant's voice is not being recorded.

Task 1 – Event-based PMT (with 30 minute delay)

DO NOT administer this test if a participant is unable to identify the money due to a severe or complete visual impairment.

- Step 1:** **At the Interview Tab in Onyx locate the Event PMT module,** click start on that row.
- Step 2:** Scan the interview ID and click **Continue**.
- Step 3:** Select the language and click **Next**.
- Step 4:** Using the instructions in Onyx:
→ Explain and demonstrate the task to the participant;
→ Repeat the instructions;
→ Verify that participant can hear the timer without difficulty;
→ Have the participant repeat the instructions; and,
→ Clarify any issues that the participant has.
- Step 5:** In Onyx complete the question(s), click **Next**.
NOTE: If participant is unable to do the test, the Event PMT module will come to an end, proceed to **Step 9**.
- Step 6:** Place the envelope to the left or right of participant according to the participant's hand preference and work surface so that the envelope is within the participant's reach but out of the way when working on other tasks.
- Step 7:** Set the timer for exactly 30 minutes.
→ Do not allow participant to see the interval of time selected.
→ Place the oven timer in close proximity to participant.
→ Ensure that the participant can't see the time left.
→ The face of the timer should be facing the interviewer.
- Step 8:** **Pause the Event PMT module.**
NOTE: The procedure to follow when the 30 minutes have elapsed is outlined toward the end of this document, following the instructions for administering **Task 4**.
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- Step 9:** **Administer the Hearing module** per the *SOP_DCS_0020 - Hearing SOP*.
NOTE: Proceed to **Step 10**: if the participant is contraindicated for the hearing test.
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- Step 10:** **At the interview tab in Onyx locate the Neuropsychological Battery module** and click start on that row.
- Step 11:** Scan participant ID and click **Continue**.
- Step 12:** Select the language and click **Next**.

Task 2 – Stroop Neurological Screening Test (Victoria version)

DO NOT administer this test if a participant has a severe or complete visual impairment.

All three sub-tasks of the Stroop **must** be completed and scoreable for this measurement to be valid. If a participant is unable to complete the first or second stimulus card do not continue with the module. In Onyx, respond '**No**' to "*Could the participant complete the task*" and Onyx will automatically skip the remainder of the test.

NOTE: The module is skipped if the participant answers 'No' twice to "Here is a sheet of paper on which you will see solid-coloured circles. We will begin with a demonstration: I will ask you to say the colour of each circle, from left to right as quickly as possible without making any mistakes. Are you ready to begin?" Document the factors that impaired performance, e.g., physical impairment, language barriers, etc.

Step 13: Read the introductions provided in Onyx regarding the subsequent tasks to the participant.

Step 14: Using the script in Onyx obtain and record receipt of the participant's consent to be recorded.

NOTE: If participant does not consent to be recorded, the application will skip over Tasks 2 and 3, and will continue with the Social Network questions, proceed to **Step 55**..

Step 15: Give the participant the headphones with microphone to put on if they have consented to being recorded.

<u>Sub-Task #</u>	<u>Sub-Task Name</u>	<u>Sub-Task Steps</u>
1	<u>Coloured dots</u>	<p>Step 16: Place the first stimulus card horizontally (there should be 4 dots across the top and 6 dots down with largest amount of void space being the bottom of the stimulus card) on the table and directly in front of the participant, facing them.</p> <p>Step 17: Read the instructions to the participant, as outlined in Onyx. Use your finger to direct the participant's eyes across the rows from left to right. NOTE: Participant may hold the card if required.</p> <p>Step 18: In Onyx complete the question and click Next.</p> <p>Step 19: Administer the demonstration, as outlined in Onyx. → If one or more errors are made, the demonstration may be re-started a maximum of 2 more times. → Even if one or more errors occur during the third attempt, proceed with the test. → Do not time the demonstration.</p> <p>Step 20: When the demo(s) is complete click Next.</p> <p>Step 21: Read the instructions to participant, as outlined in Onyx. Immediately after saying "Go" start recording the participant's response.</p> <p>Step 22: When participant has finished the task, immediately stop the timer.</p> <p>Step 23: Record in Onyx the <u>exact time</u>, to the nearest second,</p>

<u>Sub-Task #</u>	<u>Sub-Task Name</u>	<u>Sub-Task Steps</u>
		the participant took to complete this task. Step 24: Inform participant that this task is finished. Click Next .
<u>2</u>	<u>Words printed in coloured ink</u>	Step 25: Place the second stimulus card horizontally (there should be 4 words across, 6 words down) on the table and directly in front of the participant, facing them. Step 26: Repeat Step 17: to Step 24: .
<u>3</u>	<u>Interference</u>	Step 27: Place the third stimulus card horizontally (there should be 4 words across, 6 words down) on the table and directly in front of the participant, facing them. Step 28: Repeat Step 17: to Step 24: .

Task 3 – Controlled Oral Word Association Test: FAS

Step 29: Read the bold text at the top of the Onyx screen to the participant.

Step 30: In Onyx, complete the question asked, click **Next**.

Interviewers should tell participants at the start of the module that they cannot re-use the same word with a different ending. If participants do this during the test, then interviewers should caution them against continuing to do so.

Participants may respond using numbers (e.g., forty, fifty), but they cannot respond using the same number with a different ending. For example, fifty, fifty-one, fifty-two, etc. would not be acceptable. FAS_1 and FAS_2 clearly state that participants may not re-use the same word with a different ending.

Sub-Task #	Sub-Task Name	Sub-Task Instructions
1	F	Step 31: Read the bold text at the top of the Onyx screen to the participant. Step 32: Immediately after saying "Go ahead" start recording the participant's response. → If the participant is silent for 15 seconds or stops before the end of the timer, follow the script as written in Onyx. Do not help the participant. Step 33: Ask the participant to stop when the timer reaches 60 seconds and immediately stop the timer. Step 34: Record in Onyx whether or not the task was completed. Click Next .
2	A	Step 35: Repeat Step 31: to Step 34: .
3	S	Step 36: Repeat Step 31: to Step 34: . Step 37: Inform participant that the task is finished and that this is the end of the recording session.

		<p>Step 38: Have the participant remove headset.</p> <p>Step 39: **Pause the <u>Neuropsychological Battery</u> module.**</p>
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Task 4 – Choice Reaction Time Test (CRT)

DO NOT administer this test if a participant has a severe or complete visual impairment.

Discretely ensure that the participant will have enough time to complete this without being interrupted by the PMT alarm.

DO NOT commence the CRT if only 5 minutes are remaining on the timer.

- Step 40:** Ensure touchscreen device is available and set up.
- Step 41:** At the Interview Tab in Onyx locate the ****Cognitive Test** Module and click start in that row.**
- Step 42:** Make sure that the participant is seated comfortably at the table. Position the touch screen in front of participant.
- Step 43:** Choose the language and click **Next**. **The test will display on the interviewer's screen.**
- Step 44:** On the header of the test screen, right click and hold the mouse button down, drag the test window to the touch screen and maximize the window.
- Step 45:** Read the task instructions to the participant from the touch screen.
 → The participant may only use one hand when performing this task.
 → Ensure the participant understands the instructions for the task.
- Step 46:** Inform the participant that they will have practice trials. Press (or have the participant press) **Start** to administer the practice trials on the touch screen.
- Step 47:** Press (or have the participant press) **Start** to begin the second practice trial.
- Step 48:** Once practice trials are completed have participant touch **Next**.
- Step 49:** Press (or have the participant press) **Start** to begin the timed trial.
- Step 50:** Once the timed trial is complete have the participant press the **Next** button on the touch screen.
- Step 51:** Click **Finish** on the interviewer's screen.
- Step 52:** Inform the participant that this task is finished.
- Step 53:** Close the CRT Test program.

Step 54: In Onyx click **Next**, then **Finish** and **Continue** to exit.

Step 55: ****Go to the Neuropsychological Battery module, click on **Resume**** and administer the **Social Network questions**.**

Time Delay for Task 1 (Event PMT)

Step 56: When the 30 minutes have elapsed and the alarm is sounding (see **Step 6** above), allow a 60-second grace period for the participant to initiate a response. Continue administering the current module without turning off the alarm.

After 30 seconds with no response, you may turn off the alarm, but give the participant another 30 seconds to comment before giving the first cue.

NOTE: if the participant comments on the alarm, but their comment does not relate to the action that they are supposed to take, leave the alarm on for the 30 seconds and provide them the remainder of the 60 seconds before you provide the first cue. While this may be difficult, it is important to allow the participant the same amount of time to remember what they were meant to do as all other participants. Please make a note that the participant commented on the alarm.

Step 57: Using the below table, initiate the corresponding steps to complete the PMT:

Response	Steps to complete
Within 60 seconds	<ul style="list-style-type: none"> i. **Pause the <u>Neuropsychological Battery module</u>.** ii. **Click resume on the <u>Event PMT</u> module.** iii. Scan the interview ID and click continue. iv. Skip over the questions pertaining to the three cues, by selecting <i>Not applicable</i>
Doesn't respond within 60 seconds	<ul style="list-style-type: none"> i. **Pause the <u>Neuropsychological Battery module</u>** and Interrupt whatever s/he is doing. ii. **Click resume on the <u>Event PMT</u> module.** iii. Scan the interview ID and click continue. iv. Initiate provision of <u>hierarchical cues</u>, beginning with PMT_1 and PMT_1a, if applicable. v. PMT_2 and PMT_3 may be introduced in hierarchical fashion at the point(s) where the participant is unable to recall the subsequent needed action. For example, if participant responds incorrectly to PMT_1, or his/her response does not include grabbing the envelope on the desk, administer the second cue, as indicated in PMT_2. If response does not include a description of giving money to examiner or self, administer the third cue, as indicated in PMT_3. vi. Record in Onyx any behavioral observations and/or comments about the participant's performance on the task. These

	comments may be particularly useful when there is uncertainty about the score to assign to any of the scoring criteria (i.e., Intention to Perform, Accuracy of Response, Need of Reminders).
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NOTE: If the participant verbalizes an action that s/he is supposed to do (or thinks s/he is supposed to do) as part of the test, but does not do the action, say: "Please do whatever you think you were supposed to do" regardless of whether the verbalized action is correct or not.

Step 58: In Onyx select the statement that most correctly describes the participant's;
 → Intention to Perform;
 → Accuracy of Response; and,
 → Need of Reminders.

NOTE: Use the corresponding drop down menu to complete the statement if using answer 2-4 for the Need of Reminders.

Step 59: ****Close the Event-based PMT module**** by clicking **Next, Finish** and **Continue**.

Step 60: ****At the Interview Tab locate the Neuropsychological Battery module, click **Resume******.

Step 61: Scan the interview ID, click **Continue** and complete the remainder of the questions in the module.

After the Interview: Scoring Directions


Certain tests will need to be scored after the participant has left the DCS. This will require listening to the corresponding recording and entering the relevant information in the Neuropsychological Battery Scoring Module in Onyx.

Scoring – Stroop Neurological Screening Test

Step 1: Click on the  to listen to the recording of the participant's response.

Step 2: Answer the question: "Was the recording quality good enough to score?"

- If **yes**, continue to **Step 3**.
- If **no**, add a comment, repeat **Step 2** for the remaining sub-tasks.

Step 3: In ONYX,  click the boxes corresponding to any errors that the participant made.

NOTE: Spontaneous corrections by the participant are scored as correct.

Step 4: Enter the number of errors into Onyx.

Step 5: Repeat **Steps 1 – 4** of **Scoring – Stroop Neurological Screening Test** for each sub-task.

Step 6: Record any comments about the test in the notes/comments section.

Step 7: Click **Next, Finish** and **Continue**.

9.0 Documentation and Forms:

- **CRF_DCS_0019_1** - Prospective Memory Test (PMT) Case Report Form
- **CRF_DCS_0019_2** - Stroop Test Case Report Form
- **CRF_DCS_0019_3** - Controlled Oral Word Association Test (FAS) Case Report
- **CRF_DCS_0019_4** - Neuropsychological Battery Questionnaire Case Report Form

10.0 References:

- Loewenstein D, Acevedo A. The Prospective Memory Test: Administration and scoring manual. Unpublished manuscript. University of Miami School of Medicine; 2001.
- Moroni C, Bayard S. Adaptation francophone de l'épreuve du Stroop Victoria auprès de sujets âgés sains. *Processus d'inhibition: Quelle est leur evolution après 50 ans?* *Psychol Neuropsychiatr Vieil.* 2009; 2:121-9.
- Strauss E, Sherman EMS, Spreen O. A compendium of neuropsychological tests: administration, norms, and commentary. 3rd ed. Oxford: Oxford University Press; 2006.

Revision History:

New Version #	Revision Date	Revision Author	Content Approval
3.1	2015-JUN-30	Lorraine Moss	Mark Oremus
Summary of Revisions			
Made clarifying modifications throughout document.			
Added to Scoring – Stroop: Step 6: Record any comments about the test in the notes/comments section.			
Removed section Scoring Task 2: Controlled Oral Word Association Test: FAS , as DCS staff will no longer score that module.			
New Version #	Revision Date	Revision Author	Content Approval
3.0	2014-AUG-20	Lorraine Moss	Mark Oremus
Summary of Revisions			
Supplies: Stroop cards – DO NOT LAMINATE			
Added to Contraindications: Participant has a severe or complete visual impairment (event-based PMT, Stroop, Choice Reaction Time).			
Recording a Participant, Step 2: Added "Watch the computer monitor to ensure the participant's voice is being picked up on the recording. You will see the sound waves fluctuating as the participant talks."			
Recording a Participant, Step 4: Note edited to read: DO NOT stop and re-record a participant's response unless the participant's voice is not being recorded.			
Task 2: Note added: The module is skipped if the participant answers ' No ' twice to "Here is a sheet of paper on which you will see solid-coloured circles. We will begin with a demonstration: I will ask you to say the colour of each circle, from left to right as quickly as possible without making any mistakes. Are you ready to begin?" Document the factors such as physical impairment, or language barriers etc. that impaired the performance.			
Task 4: Step 45: Point added: Participant can only use one hand when performing this task.			
Task 4: Reminder edited: DO NOT commence the CRT if <u>only</u> 5 minutes are not remaining on the timer.			
Task 2 and 4: added: DO NOT administer this test if a participant is unable to identify the money due to a severe or complete visual impairment.			
Time Delay for Task 1: Step 56: added "After 30 seconds with no response, turn off the			

alarm, but give the participant another 30 seconds to comment before giving the first cue.”
 Added **NOTE**: if the participant comments on the alarm, but their comment does not relate to the action that they are supposed to take, leave the alarm on and provide them the remainder of the 60 seconds before you provide the first cue. While this may be difficult, it is important to allow the participant the same amount of time to remember what they were meant to do as all other participants. Please make a note that the participant commented on the alarm.

Scoring Task 2: Step 2 added: To indicate whether the recording is usable, answer this question: “Was the recording quality good enough to score?”. If **yes**, then continue. If **no**, then add a comment and go straight to **FAS**.

Following steps renumbered and edited for clarity.

Scoring Task 3: Step 7 added: To indicate whether the recording is usable, answer this question: “Was the recording quality good enough to score?”. If **yes**, then continue. If **no**, then add a comment.

Following steps renumbered and edited for clarity.

Documentation & Forms: New CRFs referenced.

SOP formatting updated.

Purpose, Scope, and Responsibilities sections reviewed and edited.

New Version #	Revision Date	Revision Author	Content Approval
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2.0	2013-JAN-02	Lorraine Moss	Mark Oremus
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Summary of Revisions

Inserted a line between **Steps 7 & 8; 66 & 67** in section **6.0** Procedure Steps

Removed **Step 12** in section **6.0** & re-numbered preceding steps.

Updated **Steps 16, 25, 34, 41, 45 & 49** of section **6.0** Procedure Steps to read: Read the instructions to participant, as outlined in Onyx. Immediately after saying “Go”,

- Click on the “O” radial button before the timer
- Click on the “record” button to begin recording the participant.

Added a stop button picture to **Steps 11, 16, 25, 26, 34, 35** of section **6.0**

Changed **Steps 42, 46, 50** of section **6.0** to read: “Ask participant to stop when the timer reaches 60 seconds, immediately press **Stop** to stop the timer.”

Step 38, 40, 44, 48 of section **6.0 Procedure Steps** has been changed to: “Read the instructions in bold at the top of the ONYX screen.”

Step 58 has now been revised to be **58-60** and reads as follows:

- **Step 58** – Choose the language and click **Next**. **The test will display on the interviewer’s screen.**
- **Step 59** – Right click and hold the button down on the header of the test screen, drag the test to the touch screen and maximize the test.
- **Step 60** - Read the task instructions to participant from the touch screen,

Number formatting in section **6.0** updated due to deleted and added steps

Broke **Step 71** into 2 steps for ease of reading.

Reformatted and numbered the **After the Interview: Scoring section**

Step 5 – removed the word over from in front of the word timer.

Removed “Enter password and enter reason and comment and click **Continue**.” From the end of **Step 6**.

Added “Participant may hold the card if required.” to the end of step 13

Added “Participants may respond using numbers (e.g., forty, fifty), but they cannot respond using the same number with a different ending. For example, fifty, fifty-one, fifty-two, etc. would not be acceptable. FAS_1 and FAS_2 clearly state that participants may not re-use the same word with a different ending.” under step 40

Added “**Step 41** - Interviewers should tell participants at the start of the module that they cannot re-use the same word with a different ending. If participants do this during the test,

then interviewers should caution them against continuing to do so.”

Added note under task 3

Added paragraph under step 40.

Baseline