ICPSR 4248

ACTIVE (Advanced Cognitive Training for Independent and Vital Elderly), 1999-2001 [United States]

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Form 3 Baseline Individual Assessment, Part 1 Questionnaire

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Question by Question Specifications Guide for Administration of the Individual Assessment Part I (Screening) Form 3

I. Purpose

Together with the results of the Telephone Screener, the results of the subject's performance on the measures in the Individual Assessment Part I will determine their eligibility for participation in the ACTIVE study.

II. Study Sample and Administration

Subject eligibility status will be finalized during the Individual Assessment Part I. with the completion of the Vision testing and The Mini-Mental Status Exam. The Telephone Screener <u>must</u> be completed in advance of administration of the Individual Assessment Part I Measurements.

III. Administration Protocol

The following items should be assembled in advance of the subject's appointment time.

A. Materials

- Individual Assessment, Part 1 (Screening) Form # 3 with ID label attached
- HVLT Subject Data Forms Packet #310a with ID labels attached to all pages
- Word Series Data Form #311 with ID label attached
- HVLT Recognition Data Form #312 with ID label attached
- QxQ Specifications Guide for Individual Assessment Part 1 (Screening)
- Snellen Acuity Score Conversion Table
- Subjects' Vision Report Form

B. Equipment

- 1. Sony Boom Box Model CFS-B15
- 2. The HVLT Administration Audiotape for the Baseline Visit
- 3. Pencils for subject's use
- 4. Electronic timer
- 5. Pocket calculator
- 6. Vision acuity supplies:
 - GOOD-LITE LD 10 Vision Chart
 - GOOD-LITE MODEL 600A light box
 - spare fluorescent bulb

- ten foot string
- electrical extension cord
- 7. MMSE supplies:
 - Wrist watch
 - 3 pieces of 8 1/2 x 11 inch blank, white paper for completing directives, writing a sentence and drawing shapes
 - 'Close your eyes' Show Card
 - pencil
 - 'Intersecting Shapes' Show Card
- 8. Useful Field of View (UFOV) and Complex Reaction Time (CRT) supplies:
 - computer
 - UFOV software
 - CRT software
- 9. Spare batteries should be available for all battery operated equipment.

C. Preparation

- 1. Testers must have successfully complete all requirements for Certification as an ACTIVE Tester.
- 2. Be advised, it may take as many as three workstations to complete the Individual Assessment Part I Measurements. A computer station is used for the UFOV and CRT computer tests; some testing sites may allow space for a separate station for the Good Lite Vision box for the vision testing; all other tests should be completed at one other station. If a separate station is not available for vision testing, the tester should set up the Good Lite Vision box in advance of the subject's arrival and move the box when the vision testing is completed. A desk or table with a smooth surface for writing is required for the MMSE, Word Series and HVLT testing.
- 3. It must be possible to adjust the lighting in the room in keeping with the requirements of the visual acuity testing protocol (See requirements documented in Section B below). The room must allow for a private and confidential interview and test completion with minimal background noise.
- 4. In advance of the subject's appointment time, testers should assemble a packet with all forms necessary for completion of the Individual Assessment Part I Measurements. All forms should be pre-labeled with the Subject's study ID labels.
- 5. Prior to the start of the session, the tester should set up and test equipment to be sure the necessary support (electrical outlet) and equipment are in proper working order, including the audiotape player, electronic timer, pocket calculator, GOOD LITE light box, computer and related software for the UFOV and the CRT tests. Spare batteries should be carried for all battery operated equipment.

D. Order of Administration

The ACTIVE Steering Committee has prescribed the order of administration for the tests included in the Individual Assessment Part I (Screening) Battery. The order is:

- 1. Vision
- 2. Mini Mental Status Exam
- 3. HVLT
- 4. Word Series
- 5. HVLT Recognition
- 6. BREAK POINT
- 7. UFOV
- 8. CRT

You must follow this order exactly. Ideally, the assessment can be completed in a one session. A break <u>must be offered</u> after the completion of the HVLT Recognition. It can take 30-40 minutes to complete the remainder of the assessment, so subjects should be encouraged to take even a small break to avoid a break at a later point in the battery. Nonetheless, the tester is allowed to continue the assessment if the subject refuses a break. If for any reason the tester feels the subject cannot complete the assessment in one session, the session should be stopped at the break point.

IV. Important Matters related to Determination of Subject Eligibility

Testers must strive to accomplish two critical objectives when determining subject eligibility during the Individual Assessment Part I. Specifically, the scoring must be accurate and the subject must not be made to feel uncomfortable during the scoring procedures.

A. Accuracy

You must be certain to take great care when calculating the Vision and MMSE total scores. It is critical that scores related to eligibility be calculated accurately. Each tester should calculate the Vision and MMSE total scores twice in the field for accuracy. These calculations should be checked again by another ACTIVE Field Site staff person as soon as the data forms are returned to the ACTIVE Field Center. All scores will be calculated a third time by the computer when the data are entered into the ACTIVE data management system. Errors in calculating scores related to eligibility determination can be quite consequential. Ineligible subjects who are misidentified as eligible will be randomized only to be excluded after the errors have been identified. Eligible subjects misidentified as Ineligible may be mistakenly excluded.

B. When to Complete the Scoring

DO NOT TABULATE THE SCORES WHILE THE SUBJECT WATCHES YOU. If necessary, a tester may need to leave the testing room momentarily to complete the scoring to determine the subject eligibility status.

V. Section by Section Review

Section A. Identifying Information

Items A1. - A3. should be completed by the ACTIVE tester just prior to the start of the measurement.

- **A1.** Subject ID: Affix the Subject's study ID label in the space provided.
- **A2.** Visit #: This item may be pre-coded. Form 3 will be used at the time of the Individual Assessment Part I (Visit # 10).
- **A3.** Form Version: Be sure the form version on the form matches the current approved version.

Section B. Vision

1. <u>Description</u>

Visual acuity will be measured with the GOOD-LITE LD-10 CHART IN A GOOD-LITE MODEL 600A light box. The chart is designed to be used at a 10 foot text distance. To insure uniformity of illumination, the fluorescent bulb should be replaced every two years or after 1000 hours of use. Replacement bulbs can be ordered from the GOOD-LITE company, as indicated on the yellow notice that accompanied this instrument.

The plastic eye chart can be washed with a gentle, non-abrasive detergent (such as a liquid dish soap) to remove dirt and fingerprints, but care should be taken not to scratch or disturb the matte finish. Excessive heat will warp the eye chart, so use care when storing the apparatus in closed cars during summer months. Replacement charts can be ordered from the manufacturer.

2. Administration

a. Setup

The light-box should be set on a stable surface such as a table, shelf or counter near an electric outlet. After plugging in the box, the button on top is <u>depressed and held down</u> until the bulb turns on.

The subject should be seated at eye level, 10 feet from the box. An easy way to insure the 10 foot distance between chart and subject when testing is to attach a string to the top handle which measures out 10 feet from the surface of the chart (not the handle) to the subject's eyes. When the string is extended out, this is the position of the subject. If data collection will be located in the same place for an extended time period, it may be easier to simply set up the chart in a fixed location (on the wall) and then put tape on the floor marking the 10 foot distance from the surface of the chart.

Room illumination should be dimmed. That is, turn off the overhead lights. Subdued lighting elsewhere in the room is okay. Care must be taken that no intense lighting falls directly on the chart or shines directly into the subject's eyes (e.g., from a window or overhead light source).

b. Test Procedure

All testing is performed binocularly with the subject's <u>customary indoor</u> (no sunglasses or shades) glasses used for distant vision. If bifocals are worn, the subject is instructed to look through the portion of the glasses that s/he normally uses when looking at objects that are far away. The tester should indicate on the data form whether the subject wore the correction he/she normally uses for distance vision (B11 and B12).

The script for administration appears in the form. Follow the scripts precisely.

After adjusting the distance of the subject for the 10 foot viewing distance, warn him/her that you are going to turn out the overhead lights. If there is a dramatic change in light levels (from room illumination to total darkness), the subject may need a moment to adjust.

The examiner indicates to the subject the row of letters with the large number 5 (row B4 on the data form) and asks the subject if he/she can <u>easily</u> read the letters. If so, the test begins here. If the subjects reports they <u>cannot</u> read row 5 easily, start the test at the top of the chart.

If the subject claims that he/she can easily see the letters in row 5 and you start there but the subject actually misses a letter, or appears to be straining to read these letters, the tester should start the test at the top of the chart.

Once the starting row is determined, the subject is instructed to slowly read across the row from left to right. If there is any confusion during the test, the tester may indicate, by pointing, which row is currently being tested, but should not point to individual letters in a row. If a subject cannot read any letters on the top line, record this on the scoring sheet by drawing a bold line through the entire top line.

The first time a subject says that he/she can't see a letter, the tester should encourage the subject to make their best possible guess. Use the prompt provided in the data form. Similar encouragement should be provided with subsequent hesitancy. Follow the prompts in the form.

Many subjects are often cautious and conservative about naming letters on a letter chart. It is very important that the subject respond with a letter, not "I don't know" or "I can't see it", etc. Experienced testers can often overcome the subject's hesitancy and coax some additional guesses which turn out to be correct identifications. Obviously, a tester has to get a feel for how much encouragement is warranted. Performance on the previous line is often a good guideline. For example, a subject typically doesn't go from getting all letters on a given row correct to zero letters correct on the next line.

The test is concluded when 75% or more letters are <u>missed</u> on a row (i.e. 3 of 4, 4 of 5, 6 of 7, 6 of 8, or 8 of 10). A guide is provided to the left of the row to assist testers in determining if the subject meets the criterion for the row, e.g. for B1 - B5 'If ≥ 2 ; continue'; for B6 - B8 'If ≥ 3 ; continue'. The test is concluded when this criterion has been reached.

3. <u>Coding and Scoring</u>

a. <u>Coding - Table 1: The Number Correct in each Row</u>

As the subject reads the letters aloud, the tester marks Table 1 by circling correct letters and drawing a diagonal line through incorrect letters. For each line attempted there should be either a circle or a diagonal line through each letter on that line. After the criterion for stopping has been met, the tester should draw a straight line through the middle of the letters on all subsequent lines not attempted.

Next, the tester must determine and record a code for each row in Table 1. The codes for the row should be recorded in the column labeled 'CODE' (1. - 9.) The code for the row is defined as the number of correct letters in the row called out by the subject during the test. These are the letters that the tester has circled. For each line, record the code (i.e. total number of correct letters for the row) in the space on the right at the end of each row in Table 1, labeled CODE. To assist in counting the correct letters quickly, a number guide is provided along the very top of the table. Each row in Table 1 must be assigned a code. When rows 1 - 4 are skipped (i.e. for subjects that begin the test at row 5), the totals for these rows should be recorded as the maximum possible for that row, e.g., for row 1 (B1), the total would be 4; for row 2 (B2), the total is 5; for row 3 (B3), the total is 7; and, for row 4

(B4), the total is 8. When rows at the end of the test are not administered (i.e. after the criterion has been met for the preceding row), enter a score of zero (0) for the row.

b. Scoring – Table 2: Score for the Row

Table 2 provides a guide for quick and easy scoring. Follow these steps the determine the proper vision score:

- 1. Use the code (number correct) you recorded for the row in Table 1;
- 2. Find the number correct for the row at the top of Table 2;
- 3. Read down to the appropriate row in Table 2,
- 4. Determine the (conversion) score for the row and
- 5. Record this score in the space on the right of Table 2 (labeled as the **SCORE** column), in the appropriate box labeled 1a 9a.

For example, if a subject correctly identifies 3 letters in Row B1:

- 1. Using the code 3 you assigned in B1 for row 1,
- 2. You would find the number 3 in the third column in Table 2;
- 3. Read down Table 2, column 2 to row 1;
- 4. Determine that the score for the row is 7.5 and
- 5. Finally, you would record 7.5 in the space marked 1a on Table 2.

Similarly, if the subject correctly identified three letters in Row B4, the appropriate score to be written on Table 2 would be 3.8. Again, assign the maximum for rows 1-4 if the subjects begins the test in row 5; and enter zero for rows that have not been attempted after the subject meets the 'test end' criterion . The coding and scoring must be completed immediately after vision test has ended. Scores will be converted to a Snellen Eye Chart equivalence and given to the subject prior to leaving.

c. B10 - Total Vision Score/Eligibility

The total vision score is recorded in (B10) and is the sum of all the row scores from Table 2. Carefully check and recheck your addition before recording this value. A score greater than 39 is necessary to be eligible for the study. This eligibility status is recorded in (B13). If score is 39 or less, the subject is ineligible, code 2 and follow the script to end the screener.

f. Reporting Findings to the Subject.

Locate the total vision score on the Acuity Score Conversion Table (See Attachment A). Identify the Snellen equivalent on the table. Record the Snellen score on a Subject Vision Report Form (Attachment B) and check the appropriate box for follow-up recommendations. If the subject's Snellen score is 20/30 or better (e.g., 20/25), the subject report informs them that their vision is in the normal range for their age group. If their score is less than 20/30 (e.g., 20/40), the report informs them that their vision may be able to be improved. Carefully check and recheck your calculations and the table values before recording the Snellen score.

Evomn	Λ	1
Exampl	C	1

B1.	If ≥ 2 ; continue
B2.	If ≥ 2 ; continue
B3.	If ≥ 2 ; continue
B4.	If ≥ 3 ; continue

B5. If ≥ 3 ; continue **B6.** If ≥ 3 ; continue

B7. If ≥ 3 ; continue

B8. If ≥ 3 ; continue

B10.

B9.

Table	e 1:#	Corr	ect in	the R	ow				#	Correct
1	2	3	4	5	6	7	8	9	10	
K	H	(0)	\mathbf{R}							4
\bigcirc	K	$\overline{\mathbf{Z}}$	(D)	(V)						4
0	$\overline{(\mathbf{Z})}$	N	R	(H)	(V)	(C)				5
$\overline{\mathbb{R}}$	K	\overline{z}	X	X	.Af	V	g'			1
<u>-S</u>	Đ	K	H	0	R	<u> </u>	V			0
H	0	С	Z	R	K	D	S	V	N	0
N	Z	С	0	S	K	D	V	R	Ħ	0
D	С	S	K	0	V	R	N	Н	Z	0
Z	S	V	D	K	Н	N	0	R	С	0

	Tabl	le 2:	Score	for th	e Rov	V					Score
	1	2	3	4	5	6	7	8	9	10	for Down
B1a.	2.5	5	7.5	(10)							Row 10
B2a.	2.3	4	6	8	10						8
B3a.	1.4	2.9	4.3	5.7	<u>(1)</u>	8.6	10				7.1
					1						
B4a.	(1.3)	2.5	3.8	5	6.3	7.5	8.8	10			1.3
B5a.	1.3	2.5	3.8	5	6.3	7.5	8.8	10			0
B6a.	1	2	3	4	5	6	7	8	9	10	0
B7a.	1	2	3	4	5	6	7	8	9	10	0
B8a.	1	2	3	4	5	6	7	8	9	10	0
B9a.	1	2	3	4	5	6	7	8	9	10	0

TOTAL VISION SCORE:

26.4

Exan	nple 2	Table 1: # Correct in the Row #						# Correct				
		1	2	3	4	5	6	7	8	9	10	
B1.	If ≥ 2 ; continue	K	H	0	R							4
B2.	If ≥ 2 ; continue	\bigcirc	(K)	\bigcirc	D	V						5
B3.	If ≥ 2 ; continue	0	\bigcirc	N	\bigcirc R	H	V	\odot				6
B4.	If ≥ 3 ; continue	R	K	\bigcirc	\bigcirc S	\bigcirc	\bigcirc	(V)	(D)			8
B5.	If ≥ 3 ; continue	S	Þ	K	H	<u></u>	R	K	X			3
B6.	If ≥ 3 ; continue	Ж	(0)	Z	X	R	K	'Q'	S	X	N	1
B7.	If ≥ 3 ; continue	<u>N</u>	_ <u>Z</u> _	_ <u>C`</u>	<u>-o`</u>	<u>s`</u>	<u>K</u>	_D`_	_v`	R.	<u>H`</u>	0
B8.	If ≥ 3 ; continue	-D	С	S	K	0	V	R	N	H	Z	0
B9.		7	S	V	-D -	K	H	N	0	R	-C	0

	Table 2: Score for the Row								Correct for		
	1	2	3	4	5	6	7	8	9	10	Row
B1a.	2.5	5	7.5	10							10
B2a.	2	4	6	8	10						10
B3a.	1.4	2.9	4.3	5.7	7.1	8.6	10				8.6
B4a.	1.3	2.5	3.8	5	6.3	7.5	8.8	10			10
B5a.	1.3	2.5	3.8	5	6.3	7.5	8.8	10			3.8
B6a.	1	2	3	4	5	6	7	8	9	10	1
B7a.	1	2	3	4	5	6	7	8	9	10	0
B8a.	1	2	3	4	5	6	7	8	9	10	0
B9a.	1	2	3	4	5	6	7	8	9	10	0
B10.					ТОТ	AL V	ISIO	N SCC	RE:		43.4

- Use a horizontal line (________) for all lines not attempted.
- Use a strike mark (\setminus) for letters attempted but incorrect.

Section C. Mental Status (MMSE)

1. <u>Description</u>

The Mini Mental Status Exam (MMSE) gives a brief assessment of the person's orientation to time and space, recall ability, short-term memory, and arithmetic ability. It is being used as a screening test to identify cognitive loss.

The MMSE includes 12 items, divided into two sections. The first section requires verbal responses to orientation, memory, and attention in questions. The second section requires reading and writing and covers ability to name, follow verbal and written commands, write a sentence, and copy a polygon.

2. <u>Administration/Script</u>

All questions should be asked in the exact order shown in the data form. Each question can be asked a maximum of three times unless otherwise noted. If the subject does not respond, code 0 (zero) for the item; if the subject's response is incorrect, code 0 for the item. DO NOT PROMPT THE SUBJECT IN ANY WAY. Do not cue them regarding the correct answer or indicate your approval or disappointment after they have indicated their response. For example, do not say "good" after a subject answers the question. You might say "O.K." or "Thank-you." The MMSE scoring rules are conveniently summarized for your use during testing, see Attachment C.

C1. and C2. These questions measure orientation. Ask the questions as written. Record the subject's response verbatim on the response line. Allow 10 seconds for each reply. In general, you will give one point for each correct response, record 0 if incorrect. Refer to the scoring card for specific rules. Acceptable answers for C1 and 2 appear in the table below.

Item #	Question	Acceptable Response(s)
C1a. C1b.	What year is it? What season is it?	Exact year only During the last month of the previous season or first month of the new season: accept either season, i.e • March = Winter or Spring • June = Spring or Summer • September = Summer or Fall • December = Fall or Winter
C1c.	What is today's date?	Accept exact date, previous date, or next date, e.g., on the 7th, accept 6,7, or 8.
C1d.	What day of the week is it?	Exact day only.
C1e.	What month is it?	Accept exact month. However, on the first day of the new month, or last day of previous month, accept either month. If subject gave the correct month in C1c, you do <u>not</u> need to ask for month again in C1e.

C2a. What state are we in? Exact answer only (or site-specific answer if no state).

C2b. What county are we in? Exact answer only (or site-specific answer if no

county).

C2c. What town (city) are we in? Exact answer only.

C2d. What building or place are we Accept exact name of an institution or facility if

in? appropriate. Consider the answer correct if subject gives the formal name of the building/place. If subject

gives a partial answer, e.g., "the University" or "senior center", prompt, "could you be more specific?" The

street address is not acceptable.

C2e. What floor are we in? Exact answer only.

C3. This item measures registration. The tester should name the three objects "apple," "penny," "table" taking one second to say each. Then ask the subject to repeat all three after you have said them. Circle the words in the response field as the subject repeats them. Give one point for each correct answer named on the first attempt regardless of order given. Allow 20 seconds for a reply. If the subject does not repeat all 3, give one point for each item named on the first attempt, but then repeat them until the subject learns them, up to a maximum of 5 times. That is, accept the first answer but then repeat until the subject learns them for the recall question that come later (C5). Three points is the maximum a subject can score for this question; record 0, 1, 2 or 3 in the space provided.

- **C4.** This question measures attention and calculation. Follow the directions. Stop the subject after 5 answers. Record the subject's responses in the space provided. Give one point for each correct answer. Five points is the maximum a subject can score for this question; record 0, 1, 2, 3, 4, or 5 in the space provided. If the subject makes an error, but from that number correctly subtracts 7, count those responses as correct. For example, subject says 93, 85 (incorrect), 78, 71, 64; the code would be 4 for 4 correct responses.
- **C4a.** This question is sometimes used as an alternate to C4. In this study, we will ask <u>both</u> C4 and C4a, but use only C4 in determining the total score for eligibility. Record the subject's responses in the spaces provided. IMPORTANT NOTE: THE SCORE FOR C4A WILL NOT INFLUENCE THE SUBJECT'S ELIGIBILITY STATUS. ITEM C4A WILL BE SCORED BY COMPUTER.
- **C5.** This question measures recall. Ask for the names of the three objects given in Q3., "apple," "penny," "table". Circle the words in the response field as the subject repeats them. Give one point for each correct answer regardless of order given. Allow 10 seconds for a response. Three points is the maximum a subject can score for this question; record 0, 1, 2 or 3 in the space provided.
- **C6.-C11.** The remaining questions measure language.
- **C6.** Point to a <u>pencil</u> and a <u>watch</u> (one at a time) and ask the subject to name them by asking "What is this called?" Circle the words in the response field as the subject repeats them. Give one point for each correct answer. For watch you may accept a response of 'watch' or 'wristwatch.'. These are the only correct responses. No alternates are allowed for pencil. Two points is the maximum a subject can score for this question; record 0, 1, or 2 in the space provided.

- **C7.** Ask the subject to repeat the phrase, 'no ifs ands or buts'. Give one point if correctly repeated. One point is the maximum a subject can score for this question; record 0 or 1 in the space provided.
- **C8.** This question asks the subject to follow a three-stage command. 'Take the paper in your right hand. Fold the paper in half. Put the paper on the table. Give all three components of the command as one statement. Hold the paper in front of you. Be sure to read all three commands before you give the paper to the subject. Do not extend the piece of paper all the way to the subject. Circle the commands completed correctly. Give one point for each stage correctly completed. Three points is the maximum a subject can score for this question; record 0, 1, 2, or 3 in the space provided.
- **C9.** Show the subject the card with "CLOSE YOUR EYES" written on it. Tell the subject to read the instructions on the card and do what it says to do. Give one point if the subject closes her/his eyes. If the subject just reads the card but doesn't close her/his eyes repeat... 'Read the instructions on the card and do what it says.' You can repeat this prompt up to 3 times for the subject to get credit for the response. Allow 10 seconds for the response. Score one point only if the subject closes his/her eyes. One point is the maximum a subject can score for this question; record 0 or 1 in the space provided.
- **C10.** Give the subject a piece of paper and a pencil. Ask him/her to write a sentence of his or her own choice. If subject says that they don't know what to write about, prompt: "Write a sentence about the weather." Give one point if the sentence contains a subject and a verb and makes sense. Ignore spelling errors when scoring. One point is the maximum a subject can score for this question; record 0 or 1 in the space provided. Allow 30 seconds.
- **C11.** Give the subject the paper with the polygon design on it. Present the card in the horizontal position. Ask the subject to copy it. Give one point if correctly copied. Allow multiple tries until the subject is finished and hands the paper back to you. Accept the first drawing given to you. Do not urge the subject to try until s/he gets it right. The subject must draw two, 5-sided figures, intersected by a 4-sided figure. One point is the maximum a subject can score for this question; record 0 or 1 in the space provided.

3. Scoring/Eligibility

The total MMSE score is the sum of all points assigned to each completed task or question except for task C4a. DO NOT INCLUDE THE SCORE FROM C4A IN THE MMSE TOTAL SCORE. The maximum score is 30. If a subject cannot or does not respond to or complete a task, this should be scored as an error. A score of 23 or higher is necessary to be eligible for the study. If score is less than 23, the subject is ineligible and follow script to end the screener.

Section D. HVLT Word List 1

1. <u>Description</u>

The Hopkins Verbal Leaning Test (HVLT) is a test of new verbal learning and memory. Unique HVLT word lists will be used at each study visit. The test is administered in two parts with the second part being administered after the Word Series Test. Three trials are conducted in the first part of the test. Read the Introduction and give the subject the pre-labeled packet of forms entitled "HVLT Data Forms Packet." This is a timed test. Allow precisely 2 minutes for completion of each of Trials 1-3.

2. <u>Materials / Equipment Needed</u>

- Sony Boom Box Model CFS-B15
- The HVLT Administration Audiotape for the Baseline Visit
- Electronic timer
- Pencils for subject's use
- Individual Assessment Part I (Screening) Form # 3 with ID label attached
- HVLT Subject Data Forms Packet #310a with ID labels attached to <u>all</u> pages (NOTE: The same HVLT Subject Data Forms Packet will be used for all study visits.)

3. Administration

The instructions for this task have been audiotaped for consistency in administration across sites. <u>Be certain to use the HVLT audiotape prescribed for the Baseline visit.</u> In the event of tape or cassette player failure, the tester should administer the test using the Instructions provided in Attachment D.

In the event of a mechanical failure during the test, administer using the script. Re-start the test at the beginning of the Trial in which the failure occurred, e.g., if the tape fails after the second word in Trial 2, start Trial 2 again with instructions. It is not necessary to go back to Trial 1 if the failure occurs during Trial 2 or Trial 3.

In situations where <u>interruptions</u> occur that might interfere with hearing the tape or concentration (e.g., a fire drill; someone entering the testing room; loud noise lasting more than a few seconds), rewind the tape to the <u>beginning</u> of the word list. If interruption occurs during the instructions, rewind and replay the instructions in their entirety.

4. Scoring

All other HVLT coding should be completed after the testing session is completed and the subject has left. For each word in Trial 1-3, code 1 (YES) if the subject wrote (recalled) the word, and code 2 (NO) if the subject did not write (recall) the word. The subject's total scores will be computed by the DMS.

Section E. Word Series Test

1. <u>Description</u>

This is a test of inductive reasoning in which the subject is shown a series of days of the week or months of the year and must select the next week/month in the series from among five choices.

1. Materials / Equipment Needed

- Electronic timer
- Pencils for subject's use
- Individual Assessment Part I (Screening) Form # 3 with ID label attached
- Word Series Data Form #311 with ID label attached

2. Administration

Follow the script and directions on the test form precisely. Use a copy of the test form (#311) to read the script. This is a timed test of 6 minutes. You may suggest that subjects use a ruler or card to keep their place in the test form. Be sure subjects are on the <u>last page</u> of the instructions before you tell them to turn the page and begin the test. Go over each example no more than 2 times. If the subject does not understand the pattern for the example after 2 tries, move to the next example. Once the subject starts the test, if you notice that s/he is spending a very long time on a problem, encourage her/him to move to the next problem. A long time is defined as being on problem #1, 2, or 3 at the end of 3 minutes.

4. Scoring

The Word Series data from the subject's data form will be entered directly into the ACTIVE DMS. Scores will be computed by the DMS.

Section F. HVLT Recognition

1. <u>Description</u>

The HVLT Recognition task is the second part of the Hopkins Verbal Leaning Test (HVLT) conducted earlier in the assessment. It is a test of new verbal learning and memory.

2. Materials/Equipment Needed

- Sony Boom Box Model CFS-B15
- The HVLT Administration Audiotape for the Baseline Visit
- Pencils for subject's use
- Individual Assessment Part I (Screening) Form # 3 with ID label attached
- HVLT Recognition Data Form #312 with ID label attached
 (NOTE: The same HVLT Recognition Form #312 will be used for all study visits.)

3. Administration

The instructions for this task have been audiotaped for consistency in administration across sites. <u>Be certain to use the HVLT audiotape prescribed for the Baseline visit.</u> In the event of tape or cassette player failure, the tester should administer the test using the Instructions provided in Attachment D.

In the event of a mechanical failure, continue to administer the test using the script. If in the middle of the instructions, re-read the instructions. If in the middle of the word list, start reading the script at that point in the list. <u>Do not go back to the beginning of the word list</u>.

In situations where <u>interruptions</u> occur that might interfere with hearing the tape or concentration (e.g., a fire drill; someone entering the testing room; loud noise lasting more than a few seconds), rewind the tape to the <u>beginning</u> of the word list. If interruption occurs during the instructions, rewind and replay the instructions in their entirety.

4. <u>Scoring</u>

The HVLT Recognition data from the subject's data form will be entered directly into the ACTIVE DMS. Scores will be computed by the DMS.

Section G. Useful Field of View (UFOV)

1. <u>Description</u>

The UFOV is comprised of three subtests, each of which builds on the previous subtest. The first subtest requires the subject to identify which of two objects (a silhouette of a car or a truck) was presented inside a fixation box. The exposure duration of the target is manipulated to determine a threshold value for correct identification. The second test includes a central identification task, but in addition, the subject is required to locate a peripheral target. The location of the target is varied randomly from trial to trial and once again a threshold for both the identification of the central target AND correct localization of the peripheral target is determined by manipulating the duration of exposure to the display. The third test requires the subject to perform the central identification task and the peripheral localizing task, however, the peripheral target is embedded in a field of distracters. Once again, the threshold exposure duration for correct performance of both the identification and localization tasks is determined.

2. Administration

These instructions provide general guidelines to follow during testing. They will be better understood after administering the test.

Verbal responses: You may have to remind the subject to touch the screen to respond to the questions. In the beginning, many like to respond verbally only. If the subject continues to respond verbally throughout the trials, inform her that she does not have to tell you the name of the vehicle, she just needs to touch the vehicle on the screen when she is asked to identify which vehicle was inside the white box. If she continues to make verbal responses throughout the trials, no harm is done.

Responses not timed: You may have to explain to some that their responses are not timed. It doesn't matter how long it takes them to touch the screen. It matters whether their responses are correct/incorrect.

Practice trials: For Task 1 and Task 2, if the subject does not get all four practice trials correct, repeat the practice. Depending upon his/her performance, you may want to go through the demo screens and then the practice trials again. If some of the practice trials are missed, then say "You missed a few of those exercises so we're going to review/practice some more." For Task 3, not all individuals will be able to get all practice trials correct. As long as the subject understands the task and can get half the practice trials correct, you may begin the test trials. For Task 4, where the center task changes, the criterion for moving to the actual test is that the subject correctly discriminates ³/₄ of the center task discrimination.

Task 2, 3 and 4: Since the targets are generated randomly, when going through the demonstrations, you will have to note the identity of the center target and the location of the peripheral target for each trial.

Often at this point you'll have questions whether the vehicle inside the box and the vehicle on the outside the box are the same. Inform the subject that the vehicle on the outside is always a car. He/she doesn't have to worry about what it is, but where it is. If he/she responds verbally throughout the task that the vehicle on the outside is the same or opposite of the vehicle inside the box, you may explain again that the identity of the outside vehicle plays no part in his/her score.

Starting off, you may have to lead subjects through the questions. Sometimes they want to jump to locating the outside car before answering what was inside the box. As you go through the demonstration trials, provide feedback whether the center and peripheral responses were correct. If the peripheral response was incorrect, inform the participant of the correct location.

Point out that the correct identification of the center target is more important than the correct location of the peripheral target. The trial will not count if the center target is missed, even if the peripheral target is located correctly.

Throughout Task 2, Task 3 and Task 4, if the subject misses the identity of the vehicle in the white box two or more times, remind the person to focus on the box and identify the vehicle inside.

Answers to common questions: Subjects can do the test with their glasses on or off-whichever way they are most comfortable.

Viewing distance from the screen is variable, but the recommended distance is approximately 24 inches. The subject should sit at a distance at which they are comfortable, but this distance should be comfortable to the extent that the subject can touch the screen to enter their responses.

If a subject has a physical limitation which makes it difficult for him/her to touch the screen, the subject may verbally respond and the tester may touch the screen for him/her.

Program Flow: The first screen presents the Main Menu with four options. Select the UFOV option to access the screening software. You will notice a green dot on the button for the UFOV option. In general, the green dot appears on the buttons corresponding to the normal program flow to be used during the screening.

The next screen is for the input of subject identification information. The software is set up for double entry of the information. That is, once the information has been entered, the software requires a second entry of the SAME information. The two sets of information must match EXACTLY in order to proceed.

The third screen contains copyright information. Touch the continue box and proceed. At this point you are ready to begin the actual test. To do so, read the script below, and then follow the directions on the screen. You should read the directions along with the subject. Once the UFOV screening program has been completed, select the exit button from the menu and the software will automatically move to the Complex Reaction Time (CRT) software

Reminders:

- 1. Allow the subject to use/not use eyeglasses as they choose.
- 2. Try to maintain a viewing distance of 24 inches \pm 8 inches.
- 3. When the prompts on the screen identify an object, point to that object.
- 4. Responses are not timed.
- 5. Practice Criteria:

Task	Criteria
1	4 out of 4 correct
2	4 out of 4 correct (a correct response includes both correct central
	target identification and peripheral target localization).
3	2 out of 4 correct (same definition of correct as for task 2).
4	3 out of 4 correct for central discrimination task only.

3. Tester's Script

The next test is a visual attention test called the Useful Field of View. This test will measure how well you can notice objects around you when you are paying attention to something in front of you. This ability to divide your attention and notice things to the side is needed for getting around safely in the environment.

You will go through a series of brief exercises. These exercises will become harder and harder. For each exercise, you will quickly reach a point where it will become too fast for you to see everything. This is OK. We are looking for the speed at which the exercise becomes too difficult. At this point, you will have to guess at the correct response. Guessing is OK because many times you will be correct even when you are not sure.

READ DIRECTIONS ON SCREEN.

Section H. Complex Reaction Time

1. <u>Description</u>

The Complex Reaction Test involves a measurement of how quickly a subject can recognize that one of four possible traffic signs has changed relative to the other three signs.

2. Administration

This test is administered on a computer terminal. The stimuli consist of international road signs (pedestrian, bicycle, right and left turn arrows) with and without a red slash through them. Subjects are instructed to ignore signs containing a red slash and to react to signs without a red slash. One of three reactions is required. For bicycle and pedestrian signs without a slash the subject is required to press a button on a computer mouse as quickly as possible. The action signaled by the right or left turn arrow without a slash is to move the mouse in the direction indicated by the arrow as quickly as possible. The number of stimuli on the screen at any given time ranges from three to six signs. Within a trial, the number of stimuli is held constant although the positions of the signs change throughout the frames.

The initial screen has three options - Begin, Subject Info and Exit. If the current testing session is for the same subject who has just completed the UFOV screening, select the "Begin" button. The software will pick up the identifying information about the subject from the UFOV software. If, however, you have chosen the "Bypass to CRT" option from the main menu, you must select the "Subject Info" button. If the subject has not just completed the UFOV software, it will be necessary to enter the identifying information, otherwise the current subject's performance may be attributed to the wrong subject. once you have selected either the "Begin" button, or have completed the Subject Information screen, begin using the CRT script on the computer monitor.

3. Script

Introduction: This is a traffic sign recognition test. It will measure how fast you can recognize that one sign has changed relative to other signs. This ability to notice and react to changes in objects is helpful for mobility in everyday life.

MOUSE PRACTICE: Before we begin the actual task, I want you to practice using the mouse. Let us read the directions together from the computer screen.

REMINDER: AT SOME POINT DURING THE INTRODUCTION, TRACE THE RED SLASHES TO MAKE THEM CLEAR TO THE SUBJECT.

ATTACHMENT A ACTIVE Acuity Score Conversion Table

Score	Snellen Equivalent at 10 ft.	Score	Snellen Equivalent at 10 ft.
1	20/123	51	20/39
	20/121	52	20/38
2 3	20/188	53	20/37
4	20/115	54	20/36
5	20/112	55	20/36
6	20/112	56	20/35
7	20/107	57	20/34
8	20/107	58	20/34
9			20/33
	20/103	59	
10	20/100	60	20/32
11	20/98	61	20/31
12	20/96	62	20/30
13	20/94	63	20/30
14	20/91	64	20/29
15	20/89	65	20/28
16	20/87	66	20/28
17	20/85	67	20/27
18	20/83	68	20/26
19	20/81	69	20/25
20	20/80	70	20/25
$\frac{-3}{21}$	20/78	71	20/25
$\frac{22}{22}$	20/76	72	20/24
23	20/74	73	20/23
24	20/73	74	20/23
25	20/73	75	20/23
26	20/69	76	20/22
27	20/68	77	20/22
28	20/66	78	20/21
29	20/65	79	20/20
30	20/63	80	20/20
31	20/62	81	20/20
32	20/60	82	20/19
33	20/59	83	20/19
34	20/58	84	20/18
35	20/56	85	20/18
36	20/55	86	20/17
37	20/54	87	20/17
38	20/53	88	20/17
39	20/51	89	20/16
40	20/50	90	20/16
41	20/49	91	20/16
42	20/48	92	20/15
43	20/47	93	20/15
44	20/46	94	20/14
45	20/45	95	20/14
46	20/43	96	20/14
40 47	20/44	97	20/14
47			
	20/42	98	20/13
49 50	20/41	99	20/13
50	20/40	100	20/13

ATTACHMENT B

ACTIVE

Name:	Date:/
Vision	:/
	20/30 or better The results of your vision screening test today indicate your vision is in the normal range for your age group.
	less than 20/30 The results of your vision screening test today indicate your vision may be able to be improved.

Please keep in mind that the vision screening test you received today in no way replaces a comprehensive eye exam performed by a certified eye doctor (opthamologist or optometrist). The results of this test were obtained under non-clinical conditions and may yield different values under standard, clinical conditions. This test was conducted for research purposes only.

You may wish to consider care from an eye specialist, if you are not already under the care of a

doctor for your vision.

ATTACHMENT C

ACTIVE

MMSE SCORING RULES

Question	Max Score	Rule
C1a. What year is it?	1	Exact year only.
C1b. What season is it?	1	During the last month of the previous season or first month of the new season, accept either season. March = Winter or Spring June = Spring or Summer September = Summer or Fall December = Fall or Winter
C1c. What is today's date?	1	Accept exact date, previous date, or next date, e.g., on the 7th, accept 6,7, or 8.
C1d. What day of the week is it?	1	Exact day only.
C1e. What month is it?	1	Accept exact month. However, on the first day of the new month, or last day of previous month, accept either month.
C2a. What state are we in?	1	Exact answer only (or site-specific answer if no state).
C2b. What county are we in?	1	Exact answer only (or site-specific answer if no county).
C2c. What town (city) are we in?	1	Exact answer only.
C2d. What building or place are we in?	1	Accept exact name of an institution or facility if appropriate.
C2e. What floor are we in?	1	Exact answer only.
C3. Repeat names of 3 objects.	3	1 point for each correct reply regardless of order <u>on first attempt</u> .
C4. Counting backwards.	5	5 points: all correct 4 points: 4 correct, 1 wrong 3 points: 3 correct, 2 wrong 2 points: 2 correct, 3 wrong 1 point: 1 correct, 4 wrong

C5. Remember names of 3 objects.	3	1 point for each correct reply regardless of order.
C6. Name 2 objects.	2	1 point for each correct response. Must state "pencil"; Accept either "watch" or "wristwatch"
C7. Repeat a phrase.	1	Must be an exact repetition.
C8. Follow 3-step command.	3	1 point for each instruction correctly executed.
C9. Read words and do what it says.	1	Subject closes eyes. Does not have to read out loud.
C10. Write a sentence.	1	Sentence should make sense. Ignore spelling errors.
C11. Copy a design.	1	Subject must have drawn a 4-sided figure between the two 5-sided figures.
C12. TOTAL SCORE	30	

ATTACHMENT D

ACTIVE

HVLT and HVLT RECOGNITION INSTRUCTIONS

This next section is a measure of your ability to learn and remember a list of words. For this section you will use these forms. (HAND THE SUBJECT A PRE-LABELED PACKET OF FORMS TITLED "HVLT DATA FORMS PACKET.") We will start with the form marked Number 1.

TRIAL 1: The first thing I will do is read you a list of words one at a time. Listen carefully because when I stop, I want you to write down as many of the words that you can remember on the form marked NUMBER 1. It doesn't matter in what order you write them. Just try to remember and write down as many of the words as you can. When you can no longer remember any more words, place your pencil on the table.

<u>FOR EACH TRAIL</u>, AFTER INSTRUCTIONS AND BEFORE THE WORD LIST, ASK IF THERE ARE ANY QUESTIONS. ANSWER APPROPRIATELY.

Are there any questions? I will not be able to answer questions once I start reading. Please do not talk during the test. Ready?

PAUSE 10 SECONDS. THEN READ THE WORD LIST ALOUD. USING A TIMER, PAUSE 2 SECONDS BETWEEN EACH WORD.

Seconds

LION	1
EMERALD	4
HORSE	7
TENT	10
SAPPHIRE	13
HOTEL	16
CAVE	19
OPAL	22
TIGER	25
PEARL	28
COW	31
HUT	34

PAUSE 2 SECONDS AND THEN SAY: Now write all the words you can remember.

START TIMER. AT THE END OF 2 MINUTES, SAY: Stop!

TRIAL 2: (COLLECT THE NUMBER 1 DATA FORM)

Now I am going to read the same list again. When I stop, I want you to write down as many words as you can remember, including the words you wrote down the first time. This time use the form marked NUMBER 2. It doesn't matter in what order you write them, just write as many of the words as you can remember whether or not you wrote them down before. When you can no longer remember any more words, place your pencil on the table. Ready? PAUSE 10 SECONDS, THEN READ THE WORD LIST ALOUD. PAUSE 2 SECONDS BETWEEN EACH WORD.

PAUSE 2 SECONDS AND THEN SAY: Now write all the words you can remember.

START TIMER. AT THE END OF 2 MINUTES, SAY: Stop!

TRIAL 3: (COLLECT THE NUMBER 2 DATA FORM).

Now I'm going to read the same list once more. When I stop I want you to write down as many word as you can remember <u>including the words you wrote down the first two times</u>. Remember it doesn't matter in what order you write them, just write as many words as you can remember whether or not you wrote them down before. When you can no longer remember any more words, place your pencil on the table. Ready? PAUSE 10 SECONDS, THEN READ THE WORD LIST ALOUD. PAUSE 2 SECONDS BETWEEN EACH WORD.

PAUSE 2 SECONDS AND THEN SAY: Now write all the words you can remember.

START TIMER. AT THE END OF 2 MINUTES, SAY: Stop!

RECORD THE TRIAL 3 END TIME IN D1.

HVLT RECOGNITION INSTRUCTIONS

HAND THE SUBJECT THE FORM #312.

Now I am going to read you another list of words. Some of them are from the list I read before, some of them are new words. For each of the words I read, please write down Y for YES if the word is from the original list. If the word is not from the original list, write N for NO. Again, write Y in the box if the word is from the original list and N if the word is not from the original list. You will only have time to write a Y or an N because the words will be read very quickly. Remember, do not write YES or NO, just Y or N.

AFTER INSTRUCTIONS AND BEFORE THE WORD LIST, ASK IF THERE ARE ANY QUESTIONS. ANSWER APPROPRIATELY.

Are there any questions? I will not be able to answer questions once I start reading. Please do not talk during the test. Ready?

PAUSE 10 SECONDS. THEN READ BOTH THE ITEM NUMBER AND RECOGNITION WORD LIST ALOUD. PAUSE <u>2</u> SECONDS BETWEEN EACH WORD.

1.	Horse	13.	Hut
2.	Ruby	14.	Emerald
3.	Cave	15.	Sapphire
4.	Balloon	16.	Dog
5.	Coffee	17.	Apartment
6.	Lion	18.	Penny
7.	House	19.	Tent
8.	Opal	20.	Mountain
9.	Tiger	21.	Cat
10.	Boat	22.	Hotel
11.	Scarf	23.	Cow
12.	Pearl	24.	Diamond