HALT-C Trial Q x Q

Neuropsychiatric Test Results – Cognitive Effects AS

Form # 152 Version B: 07/16/2001

Purpose of Form #152: To record the results of the battery of neuropsychiatric tests assessing cognitive function in patients participating in the Cognitive Effects Ancillary Study.

When to complete Form #152: This form should be completed only at Site 17 (University of Southern California) and Site 18 (University of Michigan) as part of the Cognitive Effects of Long-term Peginterferon alfa-2a Ancillary Study. Express patients are not eligible for the Cognitive Effects Ancillary Study.

Form #152 should be completed at the following study visits:

- **Lead-In Phase patients:** Baseline (W00) and Week 24 (W24).
- **W20 Responder Phase patients:** Week 48 (W48) and Week 72 (W72).
- **Breakthrough/Relapser patients:** Randomization visit (R00) if it is more than one month after the most recent Neuropsychiatric Testing (Form #152).
- **Randomized patients**: Month 12 (M12), Month 24 (M24), Month 36 (M36), Month 48 (M48), and Month 54 (M54).

SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided.
- If the label is not available, record the ID number legibly.

A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.

A3. Enter the three-digit code corresponding to this visit.

A4. Record the date the form was completed using MM/DD/YYYY format.

A5. Enter the initials of the Neuropsychologist who scored and reviewed the form.

Neuropsychiatric Test Administration

1. A battery of neuropsychiatric tests will be administered to all study participants at Site 18 (University of Michigan) and Site 17 (University of Southern California) to assess serial changes in cognitive function over time.

2. The full battery of neuropsychiatric tests should take approximately 60 minutes to complete.

3. A neuropsychiatry technician (NPT) will administer the battery of neuropsychiatric tests. The NPT will score the neuropsychiatric tests. Dr. Carla Back-Madruga (Site 17) and Dr. Linas Bieulauskas at (Site 18) will review the scoring.

4. Neuropsychiatric tests will be administered in the order listed on the scoring sheet using standardized written instructions per the test manuals.

5. Patients will be asked to refrain from taking medications known to adversely influence cognitive function for 48 hours before testing (e.g. sleeping pills, anti-histamines, etc).

Neuropsychiatric Test Scores

All test scores are recorded as integers except for the Selective Reminding Test and the Continuous Visual Memory Test d-Prime scores, which have two digits after the decimal point. Note that each test has a defined range of possible values pre-printed on Form #152.

Calculation of Standard Scores

- Calculate Standard Scores (SS) for each representative variable according to raw scores and means and standard deviations using the given calculations. The tables used for Standard Score calculations follow the information for each test.
- Standard scores for reaction times will not be obtained at this time.
- X = raw scores on specified items from Form #152.

SECTION B: NEUROPSYCHIATRIC TEST SCORES

B1. Enter the date the neuropsychiatric tests were administered in MM/DD/YYYY format.

B2. **Selective Reminding Test**

- Record the score for questions B2a through B2j.
- Note that the d-Prime test has a range that includes negative numbers. You must record either + or – when completing question B2g.
- Question B2k: calculate and record the Standard Score using the formula below.

Recall = Item B2a

$$SS = \frac{(x^* - \text{mean for age})\ (10)}{\text{SD for age}} + 50$$

*x+5 for males

Table B2 - Selective Reminding Test Normative Data

	Age Groups						
Variables	18-29	30-39	40-49	50-59	60-69	70-79	80-91
Recall							
Mean	128.18	124.59	125.03	121.62	114.82	105.27	97.96
SD	9.16	13.40	12.00	10.46	15.77	16.67	17.49
LTR							
Mean	122.16	118.14	118.55	112.71	101.52	89.95	77.22
SD	13.12	20.64	17.95	16.10	24.68	29.23	26.26
STR							
Mean	6.14	6.72	6.48	8.96	13.52	17.47	20.74
SD	4.82	7.59	6.72	6.40	9.52	10.47	9.62
LTS							
Mean	124.00	121.62	122.45	116.67	107.00	95.54	87.48
SD	10.47	18.36	15.64	14.52	21.79	24.86	25.26
CLTR							
Mean	115.12	107.93	107.10	101.50	88.92	69.68	54.96
SD	19.67	27.62	26.62	22.39	35.85	38.96	29.04

B3. **Continuous Visual Memory Test**

- Record the score for questions B3a through B3f.
- Note that the d-Prime test has a range that includes negative numbers. You must record either + or – when completing question B3c.
- Question B3g: calculate and record the Standard Score using the formula below.

Total score = Item B3d

$$SS = \frac{(x^* - \text{mean for age})\ (10)}{\text{SD for age}} + 50$$

Table B3- Continuous Visual Memory Test Normative Data

Age	Mean Total Score	SD
18-29	82.07	4.05
30-49	79.03	4.78
50-69	75.00	5.50
70+	74.50	5.32

B4. **Digit Span**

- Record the score for questions B4a through B4d.
- Questions B4e and B4f: calculate and record the Standard Scores using the formulas below.

Digits Forward = Item B4a

$$SS = \frac{(x - \text{mean for age})\ (10)}{\text{SD for age}} + 50$$

Digits Backward = Item B4b

$$SS = \frac{(x - \text{mean for age})\ (10)}{\text{SD for age}} + 50$$

Table B4 - Normative Data for Digits Forward and Digits Backward

Age	16-17		18-19		20-24		25-29		30-34	
	Forward	Back	Forward	Back	Forward	Back	Forward	Back	Forward	Back
Mean	6.72	4.88	6.66	5.04	6.80	5.10	6.68	5.04	6.61	4.87
SD	1.32	1.44	1.34	1.46	1.27	1.51	1.35	1.63	1.35	1.44

Age	35-44		45-54		55-64		65-69		70-74	
	Forward	Back	Forward	Back	Forward	Back	Forward	Back	Forward	Back
Mean	6.63	4.93	6.57	4.79	6.35	4.55	6.28	4.48	6.14	4.40
SD	1.31	1.49	1.38	1.42	1.45	1.56	1.42	1.44	1.39	1.16

Age	75-79		80-84		85-89		All Ages	
	Forward	Back	Forward	Back	Forward	Back	Forward	Back
Mean	6.06	4.31	5.89	4.25	5.69	4.10	6.43	4.70
SD	1.26	1.17	1.26	1.03	1.01	1.05	1.36	1.43

Note: For further information pertaining to the sample size for these tests, refer to the WAIS-III manual.

B5. **Digit Symbol**

- Record the score for questions B5a and B5b.
- Question B5c: calculate and record the Standard Score using the formula below.

Digit symbol= Item B5a

$$SS = \frac{(x - \text{mean for age})\ (10)}{\text{SD for age}} + 50$$

Table B5 - Normative Data for Digit Symbol

Age	Mean	SD
18-19	81	16
20-24	80	16.25
25-29	78	15.5
30-34	77	16
35-44	75	16.5
45-54	70	15.25
55-64	61	15
65-69	54	15
70-74	51	14.75
75-79	47	14.5

B6. **Serial Digit Learning**

- Record the score for question B6a.
- Question B6b: calculate and record the Standard Score using the formula below.

Serial digit learning

$$SS = \frac{(x\text{-mean for age/education})\ (10)}{\text{SD for age/education}} + 50$$

Table B6 - Normative Data for Serial Digit Learning

Education = 6-11		Education = 12-16	
age: 16-64	age: 65-74	age: 16-64	age: 65-74
Mean = 18	Mean = 14	Mean = 20	Mean = 20
SD = 4	SD = 5.5	SD = 4	SD = 7

B7. **Simple reaction Time**

- Record the time in milliseconds.

B8. **Choice Reaction Time**

- Record the time in milliseconds.

B9. **Trail Making Test A**

- Record the number of seconds required to complete the test for question B9a.
- Record the number of errors for question B9b.

- Question B9c: calculate and record the Standard Score using the formula below.

  Trails A= Item B9a

  $$SS = \frac{(\text{mean for age-x})\ (10)}{\text{SD for age}} + 50$$

Table B9 - Normative Data for Trail Making Test A

Age	n	Mean	SD	Range
15-17	32	23.4	5.9	15.2-39
18-23	78	36.7	9.4	12-60.1
24-32	57	24.3	7.6	11.8-46
33-40	18	27.5	8.3	16-52.7
41-64	10	29.7	8.4	16.5-42

Note: If the individual is over 64 years of age, then use the means from the 41-64 age group.

B10. **Trail Making Test B**

- Record the number of seconds required to complete the test for question B10a.
- Record the number of errors for question B10b.
- Question B10c: calculate and record the Standard Score using the formula below.

  Trails B = Item B10a

  $$SS = \frac{(\text{mean for age-x})\ (10)}{\text{SD for age}} + 50$$

Table B9 - Normative Data for Trail Making Test B

Age	n	Mean	SD	Range
15-17	32	47.7	10.4	25.4-81
18-23	78	51.3	14.6	23.3-101
24-32	57	53.2	15.6	29.1-98
33-40	18	62.1	17.5	39-111
41-64	10	73.6	19.4	41.9-102

Note: If the individual is over 64 years of age, then use the means from the 41-64 age group.

B11. **Finger tapping test**

- Record the number of taps for the dominant hand for question B11a.
- Record the number of taps for the non-dominant hand for question B11b.
- Questions B11c and B11d: calculate and record the Standard Scores using the formulas below.

  Dominant = Item B11a

  $$SS = \frac{(x - \text{mean for age/gender})\ \ (10)}{\text{SD for age/gender}} + 50$$

  Non-dominant = Item B11b

  $$SS = \frac{(x - \text{mean for age/gender})\ \ (10)}{\text{SD for age/gender}} + 50$$

Table B11 - Normative Data for Finger Tapping test

Males		Preferred Hand			Non-preferred Hand		
Age	n	Mean	SD	Range	Mean	SD	Range
15-17	17	47.6	5.8	38-55.6	43.6	4.9	33.4-51.8
18-23	44	49.5	6.9	26.6-64.6	45.4	6.9	26.8-58.6
24-32	31	50.6	6.6	38.2-66.2	46	6.1	28.8-55
33-40	12	53.4	5.9	39-61	49.8	4.7	41-57.8
41-64	4	44.4	5.8	35.8-48.2	41.4	3.5	36.6-44.4

Females		Preferred Hand			Non-preferred Hand		
Age	n	Mean	SD	Range	Mean	SD	Range
15-17	15	42.7	7.9	30.2-54	41.1	6.2	31.6-51
18-23	30	43.6	7.5	30.6-65.6	41.2	6.5	32.8-61.8
24-32	25	45.2	6.7	31-60	40.9	5.7	28.6-53.6
33-40	6	45.8	5.5	40.6-55.6	44.3	4.6	40.6-53.2
41-64	6	40.4	4.8	34.2-48.4	38.6	4.8	32-46.6

Note: For both of the proceeding tables, if the individual is over 64 years of age, then use the means from the 41-64 age group.

B12. **Wisconsin Card Sorting Test**

- Record the score for questions B12a through B12e.
- Question B12f: calculate and record the Standard Score using the formula below.

(WCST) = Item B12a

$$SS = \frac{(\text{mean for age} - x)\ \ (10)}{\text{SD for age}} + 50$$

Table B12 – Normative Data for Wisconsin Card Sorting Test Variables

	< 40 years (n=100)	40-49 years (n=19)	50-59 years (n=16)	> 59 years (n=15)
Full Scale IQ	113.9 (11.7)	112.4 (13.4)	120.3 (9.4)	109.7 (9.9)
Categories Achieved	5.6 (1.0)	4.8 (1.8)	5.6 (1.1)	4.2 (2.0)
Total Errors	21.6 (16.7)	31 (27)	20.9 (12.8)	44.1 (18.9)
Perseverative Errors	10.4 (8)	16 (13.9)	11.3 (6.9)	24.2 (12.8)
% Perseverative Errors	10.2 (5.6)	14.2 (9.6)	11.2 (4.6)	19.6 (9.2)
Nonperseverative Errors	11.2 (11.1)	15.1 (15)	9.6 (6.2)	19.9 (9.1)
Perseverative Responses	13 (9.1)	19.5 (14.9)	14.8 (9.0)	28.9 (13.7)
Trials to 1st Category	12.4 (4.7)	18 (26.7)	12.9 (5.2)	14.3 (7.0
% Conceptual Level Responses	72.8 (14.4)	64.4 (24)	70.7 (13.2)	50 (17)
"Learning to Learn"	-2.4 (4.9)	-5.9 (8.5)	-0.9 (2.0)	-5.7 (8.8)
Failures to Maintain Set	0.8 (1.3)	0.8 (1.5)	0.8 (1.1)	1.0 (1.3)

Note: Data presented as mean (SD)

B13. **Controlled Oral Word Association Test**

- Record the score for question B13a.
- Question B13b: calculate and record the Standard Score using the formula below.

(COWAT) = Item B13a

A. Adjust raw score for age and education
   1. If the raw score is greater than or equal to 10, add the appropriate value from Table 8 (x = raw score + value from Table 8).
   2. If the raw score is less than 10 no adjustment is needed to the raw score (x = raw score)

B. $SS = \frac{(x - 37.5)\quad (10)}{10.75} + 50$

Table B13 - Normative Data for Controlled Oral Word Association test

Education (years completed)	Age					
	25-54		55-59		60-64	
	Male	Fem	Male	Fem	Male	Fem
Less than 9	9	8	11	10	14	12
9-11	6	5	7	7	9	9
12-15	4	3	5	4	7	6
16 or more	-	-	1	1	3	3

Note: If the individual is over 64 years of age, then use the means from the 60-64 age group.