Dear Test Administrator,

Thank you for your interest in participating in the neurocognitive portion of NRG-CC001. We have developed a web site to assist with test administrator training. Please utilize the following instructions to access the web site, training video and associated documents. Following this outline will increase compliance with protocol requirements and facilitate rapid approval of your neurocognitive certification request.

Please obtain the following from NRG’s website and review thoroughly
1. CC001 protocol:
   a. Please read Section 2.3 to review the purpose of these endpoints
   b. Section 8.3 describes the pre-registration requirements
   c. Section 11.2 provides a brief overview of the neurocognitive tests
   d. Section 13.0 summarizes the data submission workflow
   e. Appendix II contains the “NC/QOL Endpoint Flow Diagram” that describes the timing of these tests and measures in particular
   g. Print and comprehensively review Appendix II entitled “CERTIFICATION AND ADMINISTRATION PROCEDURES FOR THE NEUROCOGNITIVE TEST BATTERY”
   h. The “Certification Worksheet for Test Administrator” can be obtained at the NRG web site (www.nrgoncology.org) for protocol CC001. Print, complete, and fax to Dr. Wefel when the certification requirements have been completed.
2. Review the “Guide to Trail Making Test Errors” at the end of this letter.
3. Review the “Test Completion Codes / Neurocognitive Assessment Verification” at the end of this letter.
4. Obtain a copy of Neurocognitive Packet 1 ("Hopkins Verbal Learning Test-Revised" (Form 1), “Controlled Oral Word Association” (Form 1), “Trail Making Test” (Part A and Part B), “TMT Data Summary Form”) and the “NRG-CC001 Blank Forms” (pages 45-48 contain the Neurocognitive Function Coversheet) from the NRG web site to access these forms. Keep these with you to reference while viewing the Training Video.
5. You now have all of the necessary forms and instructions to begin the training process. Please read the “Administration Procedures for the Neurocognitive Test Battery” document and review the HVLT-R, COWA, and TMT tests and summary forms.
6. Once you have thoroughly reviewed the test procedures and are familiar with the test forms, you may access the MDACC website.

   Please logon to the following MDACC website: http://www3.mdanderson.org/depts/nco/nctbTraining
   Enter the following Study ID: CTB29673

7. “Click” on the “Training Video” hyperlink in the text. Watch the training video, which demonstrates and describes each test, with the test forms available for reference.
8. After viewing the training video, print and complete the “Post Test” (see last page in this letter).
9. Administer a “practice assessment” on a non-patient volunteer (e.g., coworker, friend, family member).
10. Scan and email (NeuropsychologyResearch@mdanderson.org) or fax (713-794-4999) all required materials (Certification Worksheet for Test Administrator, Post Test, and the Practice Assessment with a completed “NRG-CC001 Blank Forms” [just pages 45-48 that contain the Neurocognitive Function Coversheet]) to Dr. Wefel. Your certification packet will be reviewed and you will be contacted directly if any errors are noted. You will be notified directly when you qualify as an approved examiner for NRG-CC001. CTSU will also be notified when you are approved to ensure that only NRG-CC001 approved examiners are testing subjects on protocol NRG-CC001.

Sincerely,

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GUIDE TO TRAIL MAKING TEST ERRORS
Administering the Trail Making Test requires you, the test administrator, to carefully watch the patient as they complete this test. It is common for patients to make an “error” when trying to complete Part B of the Trail Making Test. When a patient makes an error, you must quickly stop them and correct the error as explained in the Training Manual and shown on the Training Video. If the patient’s errors are not corrected, then the test is invalid and this is recorded as “institutional error.” This memo will outline the most common errors and their solutions in order to prevent incorrect test administration for the Trail Making Test.

This is the most common institutional error we see for the Trail Making Test:

Completion time: 53 secs

Looking in the red circle, you can see that the patient did not draw a line from F to 7 but rather skipped circle 7 and drew the line from F to G (the yellow highlighted line). This test data (53 seconds) is invalid because the test was not completed correctly in 53 seconds. As the test administrator, in order to prevent this error, stop the patient immediately when you see an error (for example, the line drawn from F to G instead of F to 7), but do not stop timing. Bring the patient back to the point of the error (for example, circle F), and have the patient continue the trail from there. Remember, do not stop timing.

When correcting the patient, you do not want to tell them which circle they should go to next, as you do not want to “think” for the patient. The patient must complete the task themselves. You only point out errors as they happen. Examples of appropriate language to correct the patient:

- “You made a mistake. Go back to this circle (point) and continue in the correct order.”
- “You skipped a circle.”
- “Go back to this circle (point) and try again.”

A brief reminder of the instructions after an error may also be provided if appropriate. For example, after an error during Part B you may say, “Remember – it’s first a number then a letter and so on.”

You must correct the patient at every point of error, not only the first one. For example, once you stop the patient from F to G and then the patient draws the line from F to 16, you will need to stop the patient again. Similarly, if the patient makes errors at different points in the test, point out every point of error.
In some rare cases, patients can become very overwhelmed and frustrated by their errors, typically because their neurological state is compromised to the point that they cannot adequately perform the task. If a patient cannot or will not perform the test correctly, despite additional instruction and correction, then you may discontinue testing.

To discontinue the test, stop both the patient and the stopwatch. You may say something like, “I can see that you are frustrated. Let’s stop here.” Take the pencil and the test away. Record the time at which you discontinued on the Trail Making Test Data Sheet on item #2. Also, for item #3 check the box “No, patient was tested for < 3/5 minutes” and note the last correct circle. Feel free to write a comment on the Trail Making Test Data Sheet about why the testing was discontinued.

You will also need to note in RAVE on the NCF Verification Form that the test was discontinued. If you had to stop the test because the patient could not understand the test or could not complete the test due to neurologic/cognitive deficits, then mark the reason code “test discontinued due to neurological disability”. If the patient simply refused to complete testing, then “test discontinued due to patient refusal” would be appropriate. If the patient refused testing or discontinued testing due to a non-neurologic illness, select the appropriate reason code with “patient illness” (see explanation in TEST COMPLETION CODES/NEUROCOGNITIVE ASSESSMENT VERIFICATION).

Recording test data correctly will facilitate better data analysis for the trial.

Neurocognitive function is a primary endpoint for the CC001 trial, so it is crucial that tests are administered correctly.
It has come to our attention that there may be some confusion regarding the test completion codes on the Neurocognitive Assessment Verification Form. If a subject does not complete the neurocognitive assessment, there are several different options to choose from to explain why it was not completed, including patient illness, neurologic disability, patient refusal, and institutional error. The following annotated list of reason codes provides some additional guidance about when to choose which code—in particular, how to differentiate between “patient illness” and “neurological disability”.

“Patient Illness” – The patient is unable to complete the testing due to a medical illness (for example, nausea, fatigue, fever).

“Neurological Disability” – The patient is unable to complete the testing because their neurological deficits (for example, cognitive dysfunction, aphasia that prevents attempting the test, hemiparesis, acquired blindness) make them unable to perform or comprehend the cognitive testing. Some patients will refuse or discontinue testing because their neurologic deficits make the testing too frustrating – this should be indicated by using the “Neurological Disability” code.

“Patient Refusal” – The subject refused to come to the appointment or refused to attempt the test (see above if relevant).

“Institutional Error” – The test was not administered per the standardized instructions or the test administrator failed to administer the test.
1. On Free Recall (Part A) of the Hopkins Verbal Learning Test – Revised, words are read at a rate of:
   a. 1 word every 1 second
   b. 1 word every 2 seconds
   c. 2 words every 1 second
   d. 2 words every 2 seconds

2. On the Hopkins Verbal Learning Test – Revised, the length of the delay interval between Free Recall (Part A) and Delayed Recall (Part B) is approximately:
   a. 10 minutes
   b. 15 minutes
   c. 20 minutes
   d. 30 minutes

3. True or False: After the delay interval on the Hopkins Verbal Learning Test – Revised, you read the word list again before administering the Delayed Recall (Part B).

4. On the Trail Making Test, the maximum time allowed for Parts A and B, respectively, is:
   a. Part A= 3 minutes, Part B= 5 minutes
   b. Part A= 3 minutes, Part B= 3 minutes
   c. Part A= 5 minutes, Part B= 5 minutes
   d. Part A= 5 minutes, Part B= 3 minutes

5. The score for the following HVLT-R Delayed Recognition (Part C) Example is:
   Number of “UPPER CASE” words answered ‘Yes’: ________
   Number of “lower case” words answered ‘Yes’: ________  

   ![Delayed Recognition Table]

6. True or False: If the patient makes an error on the Trail Making Test, you stop timing and correct their error. You then resume timing when they restart the test.

7. How long are patients given for each letter on the Controlled Oral Word Association test:
   a. 2 minutes
   b. 1½ minutes
   c. 30 seconds
   d. 1 minute

8. True or False: On the Controlled Oral Word Association test you record patient responses verbatim and indicate errors by crossing out the response with a single line, initial and date in the margin.

Please email this posttest to Dr. Jeffrey Wefel at NeuropsychologyResearch@mdanderson.org. Thank you!