



6 Month Follow Up

Local Outcomes Examiner Training

Kim Boase

University of Washington



Welcome to BOOST Outcomes Certification

There are several steps in the 6 Month Outcome Certification process and in maintaining the certification once it is received.

Review the Outcomes Manual of Procedures (MOP)

Complete this Power Point presentation

Most slides have audio. Click on the icon to activate. (If audio is unavailable the script is included below in the notes section)

Review videos demonstrating the administration of the Neuropsychological Tests
(GOAT, RAVLT, Trails, Symbol Search and Coding)

Practice administering the test battery with co-workers or friends.

Video tape a mock administration of the test battery. This will be submitted for review.

(GOAT, RAVLT, Trails, Symbol Search and Coding)

Videos and source documents should be uploaded to OneDrive

Certification is maintained as long as an examiner completes a full in-person outcome evaluation at least once in a 6 month time span. If more than 6 months elapses then another video will be requested.



Introduction to Outcome Evaluations

We have 2 goals:

- Obtain complete and valid data at the 6 month evaluation
 - Study coordinator documents pre-injury information
 - Well-trained outcome examiners
 - Data quality checks
- Excellent follow-up rates
 - Monthly follow up calls
 - Updated contact forms



Outcome Battery and Order of Administration

Galveston Orientation and Amnesia Test – GOAT
FSE/GOSE/Interview (via phone with a Central Examiner)

Rey Auditory Verbal Learning Test - RAVLT
Trails A and B
Symbol Search
Coding

Rivermead Post Concussion Symptom Checklist
Brief Symptom Inventory 18
Satisfaction with Life

RAVLT 20 minute delay



Outcome Evaluation Basics

Local Outcomes Examiner MUST remain blinded to the treatment arm assigned to each participant.

Outcome evaluations are a one-on-one activity.

Follow test protocols and procedures carefully.

Test instructions are to be given word for word – not paraphrased. Instructions for each of the outcome measures can be found in section 9 on pages 21-23 and 55-66 of the Outcomes MOP.

Always clarify instructions before beginning the test if it appears the participant may not understand.

Timing must be exact.

Giving feedback/encouragement



Preparing for the Evaluation

Review instructions and protocols if it's been awhile since you last tested.

Confirm the appointment with the Central Examiner. Alert the CE to any unique circumstances in regard to the participant and their recovery.

Confirm space availability.

Prepare test packet: Print test forms – insert Symbol Search, Coding and BSI-18 into their proper order in the test packet if this has not been done by the study coordinator.

Gather test materials: Stopwatch, Clipboard, writing utensils, test cue cards.



Confirming Pertinent Pre-Injury Information

It may be the Local Outcome Examiner's responsibility to obtain the required pre-injury information either while the participant is still in the hospital or during the monthly calls.

The required Pre-Injury information is found on the Demographics form

- *Ethnicity and Race will be collected.

- *Level of Education: the completed years of education should be consistent with the level of education or degree obtained.

- *Work / Student Status: This variable is necessary for the completion of the GOSE-TRACK and the FSE

- *Language: Record the language, when known, spoken by the participant and if an interpreter will be necessary to complete the monthly contact calls and the 6 Month Outcome Evaluation.



Assessing Level of Education

Education is assessed 2 ways which should be in agreement: Years of completed education and highest degree obtained.

Examples:

- *If someone were to say they have 4 years of college but no degree they would be coded as having 1-3 years of college (level) with a total of 13-15 total years depending on what is complete.
- *To get credit for 12 years of education they need to have earned their High School diploma.
- *To get credit for 16 years of education they need to have earned their BA or BS.
- *To get credit for 18 years of education they need to have earned their MA or MS.
- *If someone has earned their GED ask how far they went through high school and record as the number of years completed.

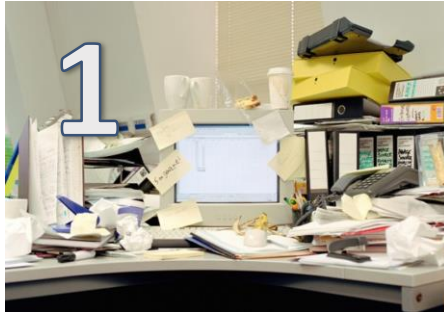


Years of Education: _____

Level of Education:

- ___ 0-8 (0-8)
- ___ 9-11 (9-11)
- ___ GED (0-11)
- ___ High School Diploma (12)
- ___ Vocational School – non academic (12)
- ___ 1-3 years of college; AA degree; no degree (13-15)
- ___ Bachelor degree or 1 year graduate school (16-17)
- ___ Master’s Degree or 1 year post grad (18-19)
- ___ JD degree (19)
- ___ MD, DDS, PhD (20)

The Test Setting



Chairs ~ table ~ clear working surface
Quiet and private
Comfortable ~ free of distraction and clutter
Accessible ~ Examiner sits across from participant.



Introducing the Central Examiner

The outcomes appointment:

Introduce yourself and thank the participant for their help in the study.

Let them know what the evaluation will be like.

Introduce the Central Examiner and explain their role in the study. Saying something like,

Hello _____. My name is _____. I'm going to be working with you today to complete the last phase of the study you have been helping with. I'm going to be asking you some questions about your recovery and how you are doing in your day to day life. We will also be completing some tasks that look at how well you can remember, concentrate and problem solve. Some of those tasks will seem easy for you, others are likely to be more challenging. No one is expected to get them all correct. You just do the best you can. The appointment should take an hour to an hour and a half. You can take a break if you need to.

Also, today, another member of the study team will be joining us by phone to ask you some questions about your recovery. Her name is _____. I'm going to call her and together we will complete a few of the measures I just told you about.



Galveston Orientation and Amnesia Test (GOAT)

Will be used as an orientation task to determine testability.

It will be administered to all participants – either in person or over the phone.

If the participant earns 24 or fewer error points on the standard administration, testing will proceed as usual. If there are 25 or more error points assessed the participant will not undergo further testing. The FSE, GOSE and the interview will be completed with an informant.

If the written version is administered, questions 7 through 10 are omitted. 20 or more error points indicate the participant will not undergo further testing. The FSE, GOSE and interview will be completed with an informant.

In an effort to eliminate the possibility of forwarding Protected Health Information (PHI) the examiner can write “OK” for the participant’s name and date of birth (questions 1 and 2).

Questions 7 and 9: Any plausible event is acceptable. 8 and 10: Ask for more detail so it’s evident the participant is recalling a specific event or a specific memory.



GOSE-TRACK and the FSE

The GOSE and the FSE will be done 2 ways – ‘All’ rating is the primary outcome. For both measures the TBI rating is secondary.

They will be completed by one of 4 Central Examiners, via phone, preferably during the 6 month outcome evaluation.

It is necessary for Local Outcome Examiners to understand the basics of the measures for 2 reasons. One, they need to recognize if pertinent information is disclosed during the remainder of the evaluation.

Secondly, they may need to recommend the Central Examiner speak with an informant even if the GOAT was within normal limits.

The Local Outcome Examiner will be present during the administration of the GOSE-TRACK and the FSE by the Central Examiner. It is recommended they follow along and take any pertinent notes that may prove useful to the final rating of the measures.

Administration information can be found on pages 24-55 of the Outcomes MOP.



Rey Auditory Verbal Learning Test (RAVLT)

Test Guidelines

Examiner reads the word list with a 1 second pause between each word. The entire list should take approximately 20 seconds to read.

Examiner records words verbatim or checks words off as they are recalled.

Short and Long delays: make sure they know it is only words from the first list that should be recalled.

Do not administer this test through the use of an interpreter. We have test forms translated to Spanish and French if both participant and examiner speak those languages.

Do not administer this test over the phone. It can be administered on video Skype or FaceTime.

Problems in Administration

Participants who recite quickly: the examiner needs to practice to keep up.

Participants who give up quickly: some encouragement may be needed to keep trying, either trying to remember more words in a trial or to continue to the next trials.

Make sure the participant understands they are to include words they have already said in previous trials.



Trails A and B

Test Parameters

Timing is continuous. Do not stop the watch to handle errors.

Because the watch does not stop, catching and handling errors quickly is important as they add to the final time.

Part A will be discontinued at 100 seconds

Part B will be discontinued at 300 seconds

If a participant is nearly finished with the task it's usually best to allow them to finish even if it goes over the time limit.

Note the time as indicated on the stop watch.

Minutes: Seconds: Hundredths

Problems in Administration

Impulsive patients: Tell them that since the measures are standardized you need to give the full instruction even though you can see they understand what to do.

If unable to complete Sample A discontinue the test.

Hand covering a circle: the examiner is not allowed to cue them to move their hand or arm.

Drawing lines 'backwards' (eg from 4 to 3; 5 to 4 etc.): Encourage them to draw lines TO the next number or letter.



Symbol Search

Test Parameters

Clarify instructions as necessary.

Timing must be exact. The subtest allows 120 seconds (2 minutes). NOT 1 minute 20 seconds (80 seconds).

Be certain the participant understands the importance of speed as well as accuracy.

Scoring: Add the number of CORRECT responses. Add the number of errors. A skipped item does not count as an error.

Problems in Administration

It is OK to clarify that the shapes need to be exactly the same. If the shape is reversed it is not the same (demonstration item 3 or sample item 2).

It is OK to clarify there will be either one shape or neither shape, never both should the participant ask.

Turning the page: If a participant has peripheral difficulties which will significantly slow them down, it is OK for the examiner to assist in turning the page.



Coding

Test Parameters

Timing must be exact. 120 seconds is allowed for this measure.

Items must be completed in order, always working from left to right.

Scoring: Add the number of correct responses.

Responses that are reversed or otherwise incorrect are not counted in the total.

Sometimes a participant may accidentally write the letter A for the ^ symbol associated with #3. We accept this as correct.

Problems in Administration

If a participant retraces lines or appears to sacrifice speed for neatness cue them to go as fast as they can, don't worry about how neatly a symbol is drawn.

Don't allow them to erase. This too, slows them down. Encourage them to write over the existing error.

Field cut/left neglect: It is OK to remind participants to look left, scan the entire page or reposition the test form if visual field deficits are an issue.



Psychosocial Questionnaires

Rivermead Post-Concussion Symptoms Questionnaire

Brief Symptom Inventory

Satisfaction with Life Scale

Present the full instructions for each measure.

If it is clear the participant is able to read and respond to the questions on their own they should be allowed to do so.

If they require assistance the examiner should read items and/or record responses.

A family member or friend should not be the one assisting them.

Review each form for completeness before moving on.



Suicidal Ideation and Intent

Each site will develop a protocol for helping those participants in which suicidal ideation or intent could be a danger.

The implementation of this protocol is triggered by the response of 'a little bit' or more on #17 on the Brief Symptom Inventory (I have thoughts of ending my life).

It can also be triggered any time the examiner has concerns about the participant's safety due to other cues or red flags encountered during the evaluation.

The study coordinator and PI at your site should be made aware and any necessary documentation completed if this is part of the established protocol.



Testing Off Site

Testing in someone's home can present unique challenges. You want similar conditions to what would be arranged elsewhere but there may be family members, pets, phones, TVs and other distractions to try to avoid.

Letting family members know what you will need beforehand will give them time to prepare a space for you to work.

Ask for some uninterrupted time – about 60 – 90 minutes.

Ask for a quiet room where distractions could be kept to a minimum. Often a dining room table works nicely.

The same can apply to a medical facility or nursing facility. Often they will have a library or other private room you could reserve.

Make sure you have all the test materials. Its easy to forget those items that are usually easily available.

If you test off site often enough it is handy to put together a 'to-go' bag.



Working With An Interpreter

Your site will need to be prepared to schedule an in-person or phone interpreter.

Instruct the interpreter to translate instructions just as you say them. Let them know they are not to provide added 'help'. If the participant asks a question they should relay the question to the examiner.

The RAVLT will not be administered through an interpreter. The other 3 neuropsychological measures should be OK – Trails A and B (if the alphabet is the same), Symbol Search and Coding.

If you are working with an interpreter over the phone but your participant is there in person you will point out and complete the examples on the Neuropsychological measures as usual.



Scheduling time with a Central Examiner

A Google calendar has been created for the purpose of scheduling with a Central Examiner. Each Study Coordinator and Local Outcome Examiner will be provided with a link and an invitation to join the calendar.

The Central Examiners will indicate the times they are available to assist. Enter the site name and participant study number on the calendar. If there is overlap between 2 Central Examiners you will need to enter the name of the Central Examiner as well.

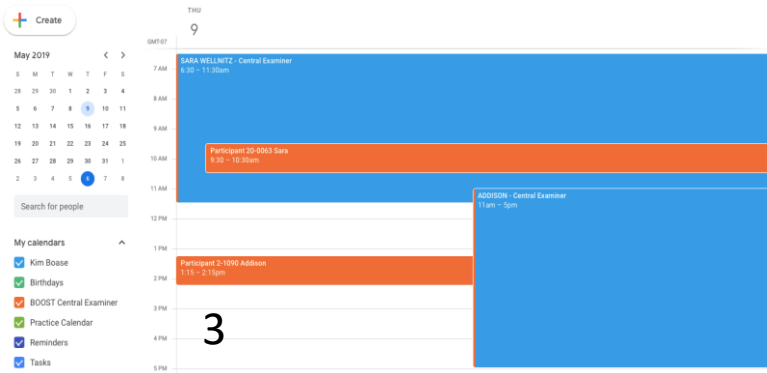
One CE is fluent in Spanish. If your participant is Spanish speaking attempt to schedule this examiner.

You will need to touch base with the CE before the appointment to confirm the time and provide them with any information which might be helpful in the administration of the GOSE-TRACK.

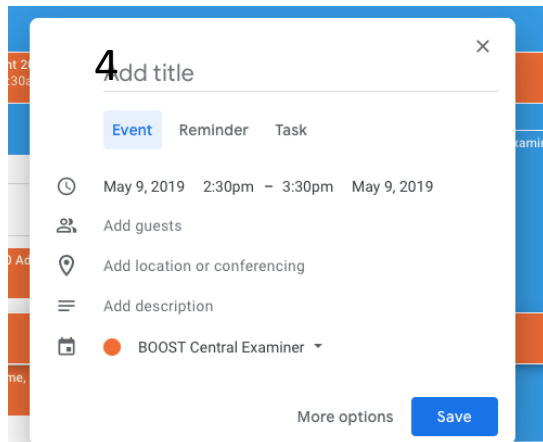
If a participant cancels an appointment far enough in advance simply remove it from the calendar. If it is short notice, please call the Central Examiner to let them know.



Schedule Using Google Calendar



1. Log into Google Calendar
2. Locate date and time of appointment.
3. Click on it (white space)



4. Add title: Enter Site name, Patient ID, Central Examiner name you are scheduling with.
5. Click save.



Scheduling the 6 Month Outcome Evaluation

At some sites scheduling the 6 Month Outcome may be the responsibility of the Local Outcome Examiner.

- *Try to schedule early in the window

- *Confirm that the participant has transportation to the appointment. If appropriate arrange transportation for them such as a taxi or Uber.

- *When scheduling a participant in a care facility, you will need to try to determine if the participant is testable, are they able to communicate over the phone? You may need to provide some documentation of the participant's participation in the trial in order to talk with a care team member at the facility.

See sections 2.0 and 3.0 on pages 6-9 of the Outcomes MOP for tips in participant retention and scheduling.



Quality Assurance

It is important that the Outcome evaluations be conducted in the same way at every site and that all the data collected is valid and entered correctly into the database.

Video recordings of the first 2 evaluations for each examiner will be uploaded to One Drive for review by the Central Outcomes Team at the University of Washington. Feedback will be provided as appropriate.

Source Documents will be uploaded to One Drive and double checked. Feedback will be documented through WebDCU. Open the Data Management tab and click on DCR.

Data entry will be double checked.

Monthly conference calls will be scheduled to discuss any issues that arise.

The UW Outcomes Team is here to address any questions you have or difficulties that arise.



Contacts

Data Quality and Examiner Certification

Joanie Machamer 206-744-9357

machamer@uw.edu

Kim Boase 206-616-0340

kboase@uw.edu

Central Examiners

Sara Wellnitz 206-744-9319

wellnitz@uw.edu

Luis Gonzalez 713-797-7106

luis.Gonzalez@memorialhermann.org

Shared Central Examiner Email and Phone

Email: boostce@uw.edu

Outcome Investigators

Nancy Temkin, PhD

temkin@uw.edu

Sureyya Dikmen, PhD

dikmen@uw.edu