TRACK-TBI
Transforming Research and Clinical Knowledge in Traumatic Brain Injury
International Traumatic Brain Injury Research Initiative

# Standard Operating Procedures for Outcome Assessment

# Version 10

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## APPROACH TO OUTCOME ASSESSMENT

### Description of the Flexible Outcome Assessment Battery

The Flexible Outcome Assessment Battery is designed to assess multiple outcome domains across all phases of recovery in patients at all levels of TBI severity. The battery is comprised of measures (see http://www.commondataelements.ninds.nih.gov/tbi.aspx#tab=Data_Standards) included in the TBI Common Data Elements and supplemented with others that were selected to address the specific aims of the study. The battery is intended to improve the granularity and breadth of TBI outcome assessment by using a flexible approach that enables assessment of basic neurocognitive function in subjects too impaired to undergo standard neuropsychological testing and, for those with adequate cognitive function, extends the assessment to include a broad range of cognitive, mental health, social participation and quality of life measures. Subjects with persistent confusion or disturbance in consciousness who are unable to participate in standardized psychological and neuropsychological testing should be assessed using the *Abbreviated Assessment Battery (AAB)*. The AAB consists of a standardized neurobehavioral rating scale developed specifically for patients with disorders of consciousness (i.e. Coma Recovery Scale- Revised [CRS-R]) and an index of confusion extracted from the Confusion Assessment Protocol (i.e. CAP Cognitive Impairment subscale [CAP-COG]). Subjects deemed appropriate for standardized neuropsychological testing and self-report measures will be assessed using the *Comprehensive Assessment Battery (CAB)*. The CAB is comprised of measures of cognition (i.e. attention, memory, information processing speed, executive functions), mood (i.e. depression, anxiety), social participation, subjective well-being and post-traumatic stress. Global functional status measures are included in both batteries. To determine whether the *AAB* or *CAB* should be administered at the initial 2-week follow-up, the examiner administers a brief test of speech intelligibility to ensure that the participant can speak intelligibly at the sentence level. The determination of which battery to administer and what test to begin with during the 6 and 12-month in-person follow-ups depends upon which battery was administered during the prior assessment and what test was administered last (see the Outcomes Battery Flowchart for additional directions). A telephone follow-up, comprised of an interview with the patient and/or surrogate and two global outcome measures, is conducted at 3 months. Participants who are no longer in post-traumatic amnesia will also complete a panel of self-report measures concerning physical, cognitive, social and emotional functioning during the 3-month telephone follow-up. Participants who are non-verbal at the time of the 3-month follow-up will not be assessed on the screening, AAB or CAB measures. In these cases, only the Surrogate version of the Interview and global outcome measures (i.e. R-GOSE, E-DRS-PI) will be administered.

### Schedule of Assessments

The measures included in the *Screening Protocol, Abbreviated Assessment Battery, and Comprehensive Assessment Battery* are summarized in the Flexible Outcome Assessment Battery Framework Table. Note that the measures are listed by outcome domain, not by order of administration. The order of test administration appears here. The table also provides information concerning the estimated administration time for each measure, the follow-up points at which each measure is to be repeated (based on cohort assignment), and whether the measure is to be administered in-person or by telephone. *Note that data collection for the Brief Assessment (BA) cohort should not begin until UCSF gives approval.* For the BA cohort, only the R-GOSE will be administered at all four follow-up time points. It is the **only** outcome measure that is to be administered to the BA cohort.

Each follow-up assessment is associated with a defined period of time during which outcome data must be obtained (i.e. “follow-up window”). For follow-ups that include an MRI scan (e.g. Comprehensive Assessment cohort at 2 weeks), the outcome assessment window is linked to the date of the MRI scan.

All other follow-ups are linked to the date of injury. For example, for participants in the Comprehensive Assessment + MRI cohort, the 2-week outcome assessment may be conducted up to 3 days before or after the MRI is completed, and up to 14 days before or after completion of the 6-month scan. Sites should make every effort to, a) schedule the MRI on or as close as possible to days 14 (2 week follow-up) and 180 (6 month follow-up), and b) complete the outcome assessment on or as close to the day of the scan as possible. The outcome assessment windows for both cohorts (i.e. Comprehensive Assessment + MRI and Comprehensive Assessment without MRI) are outlined in the table below.

Schedule for Follow-up Assessment Windows

| **2 Week Follow-up Assessment Windows** | |
|---|---|
| CA + MRI Cohort | MRI: 14 days post-injury ± 4 days |
| | Outcomes: ± 3 days of 2-week MRI |
| CA/BA Cohorts | Outcomes: 14 days post-injury ± 4 days |

| **3 Month Telephone Follow-up Assessment Window** | |
|---|---|
| All Cohorts | Outcomes: 90 days post-injury ± 7 days |

| **6 Month Follow-up Assessment Windows** | |
|---|---|
| CA + MRI Cohort | MRI: 180 days post-injury ± 14 days |
| | Outcomes: ± 14 days of 6-month MRI |
| | BTACT: ± 7 days of Outcomes (but not on the same day) |
| CA/BA Cohorts | Outcomes: 180 days post-injury ± 14 days |
| | BTACT: ± 7 days of Outcomes (but not on the same day) |

| **12 Month Follow-up Assessment Window** | |
|---|---|
| All Cohorts | Outcomes: 360 days post-injury ± 30 days |

There may be occasions in which the subject is unwilling or unable to return for in-person follow-up assessment. Under these circumstances, it is permissible to administer the Patient/Surrogate Interview and the self-report measures (i.e., R-GOSE, E-DRS-PI, Post-Concussive/TBI-Related Symptoms, Participation, Quality of Life, Psychological Health) by telephone. If the examiner suspects or encounters difficulty scheduling the in-person visit within the appropriate assessment window, every effort should be made to obtain these measures by telephone as soon as the window opens. The examiner should also continue efforts to schedule the in-person visit to administer the cognitive measures until the window closes. In situations in which the window closes before all of the outcome measures are obtained, and the subject indicates willingness to complete the assessment, the examiner should email Dr. Sabrina Taylor (Sabrina.Taylor@ucsf.edu) to request permission to complete the assessment outside the window. The email should include a brief description of the circumstances that led to the delay, and should spell out the original due dates for the MRI and outcome battery, the outcome measures that were not completed and the anticipated completion date of these measures. The request will be triaged by the Executive Committee and a decision will be communicated within two working days of the request. The overarching objective is to acquire as many of the outcome metrics as possible (using telephone administration when necessary) within the specified assessment window.

## Flexible Outcome Assessment Battery Framework Table

| Domain | Outcome Measure | Estimated Completion Time | Comprehensive Assessment (CA) Cohort | Brief Assessment (BA) Cohort |
|---|---|---|---|---|
| **Screening Protocol (5-9 minutes)** | | | | |
| Screening | • Assessment of speech intelligibility<br>• Galveston Orientation and Amnesia Test (Standard, Written, and Modified GOAT)<br>• Post-traumatic amnesia (PTA) assessment | 2m<br>5m<br><br>2m | 2W, then as needed | N/A |
| **Abbreviated Battery** (AAB) **(60-85 minutes- includes screening)** | | | | |
| Participant/ Surrogate Interviews | • Sections:<br>• Demographic Variables<br>• Vocational History<br>• Pre-morbid medical history<br>• Prior TBI screen<br>• Alcohol Use Disorders Identification Test (AUDIT-C)<br>• 3-Item Drug Use Interview | 15 min | 2W, 3M (T), 6M, 12M | N/A |
| Consciousness and Basic Cognition | • Confusion Assessment Protocol (CAP)<br>• Coma Recovery Scale Revised (CRS-R) | 15m<br>15-30m | 2W, 6M, 12M | N/A |
| Global Outcome | • Revised-Glasgow Outcome Scale Extended (RGOSE)<br>• Expanded Disability Rating Scale Post-Acute Interview (E-DRS-PI) | 8m<br>5-15m | 2W, 3M (T), 6M, 12M | RGOSE **only**<br>2W (T), 3M (T), 6M (T), 12M (T) |
| **Comprehensive Assessment Battery** (CAB) **(136-148 minutes- includes screening; excludes BTACT)** | | | | |
| Global Outcome | • Revised-Glasgow Outcome Scale Extended (RGOSE)<br>• Expanded Disability Rating Scale Post-Acute Interview (E-DRS-PI) | 8m<br>5-15m | 2W, 3M (T), 6M, 12M | N/A |
| Participant/ Surrogate Interviews | • Sections:<br>• Demographic Variables<br>• Vocational History<br>• Pre-morbid medical history<br>• Prior TBI screen<br>• Alcohol Use Disorders Identification Test (AUDIT-C)<br>• 3-Item Drug Use Interview | 15 min | 2W, 3M (T), 6M, 12M | N/A |
| Cognition | • Rey Auditory Verbal Learning Test II (RAVLT)<br>• Trail Making Test (TMT)<br>• Wechsler Adult Intelligence Scale IV Processing Speed Index (WAIS-IV PSI)<br>• NIH Toolbox Cognitive Battery<br>• Brief Test of Adult Cognition by Telephone (BTACT) | 15m<br>5m<br>4m<br><br>30m<br>20m | 2W, 6M, 12M<br><br><br>----------<br>6M (T) | N/A |
| Post-Concussive/TBI-Related Symptoms | • Rivermead Post-Concussion Questionnaire (RPQ)<br>• Participant Reported Outcome Measurement Information System Pain Intensity and Interference Instruments (PROMIS-PAIN)<br>• Insomnia Severity Index | 6m<br>5m<br><br>3m | 2W, 3M (T), 6M, 12M | N/A |
| Participation and Quality of Life (QoL) | • Quality of Life After Brain Injury- Overall Scale (Qolibri-OS)<br>• Mayo-Portland Adaptability Inventory- (MPAI4-PART)<br>• Satisfaction With Life Scale (SWLS)<br>• SF-12 Version 2 | 2m<br><br>5m<br>3m<br>3m | 2W, 3M (T), 6M, 12M | N/A |
| Psychological Health | • PTSD Checklist (PCL-5)<br>• Brief Symptom Inventory 18 (BSI18)<br>• Participant Health Questionnaire- 9 (PHQ-9)<br>• Columbia Suicide Severity Rating Scale (C-SSRS)*<br>(*Only required if ≥1 on #9 [PHQ-9] or #17 [BSI-18]) | 6m<br>6m<br>5m<br>5m | 2W, 3M (T), 6M, 12M | N/A |

## General Test Administration Guidelines

The goal of TRACK-TBI Outcome Assessment is to use standardized procedures to objectively and reliably assess the participant's functional status, cognitive abilities, mental health, social participation, quality of life, and the economic impact of the injury without placing undue burden on the participant. Because the examiner can influence testing to some degree even when standardized procedures are used, it is desirable to have the same examiner conduct all assessments during the course of this protocol. As with any neuropsychological testing, it is important that the testing takes place at a desk or table, in a quiet room, free of distractions. If possible, the examiner should be positioned at a 90° angle from the participant to allow for simultaneous monitoring of attentional focus and responses to test items. Before testing, question the participant about the ability to hear and see and make sure the participant is wearing needed corrective eyeglasses or hearing aids. Unless otherwise specified, it is permissible to repeat the instructions and questions as needed. The examiner should use his/her judgment in deciding when it is necessary to repeat instructions, questions and response options. This will vary across participants.

The skill and judgment of the examiner often affect the participant's willingness to be tested and the effort he/she invests. Thus, during an actual test session the examiner must simultaneously administer tests, observe and assess participant behavior, and make necessary adjustments. The following guidelines are provided to maintain inter-rater reliability and ensure standard administration of the outcome assessment for the TRACK-TBI protocol. Following these guidelines at your site will help generate valid and accurate measurements while reducing stress and discomfort for participants.

## Examiner Qualifications and Battery Certification

All personnel involved in outcome assessment must complete CITI and HIPAA training in accord with local IRB requirements, undergo specialized training in administration of all the measures included in the Flexible Outcome Assessment Battery and be approved by the Site PI prior to assuming testing responsibilities. Certification of all staff with responsibilities for outcome data collection will be conducted through review of videotaped simulated assessments and completed CRFs. After reviewing the TRACK TBI Outcome Assessment training materials provided, staff members should prepare two videotapes- one demonstrating how to administer all the measures in the Screening Protocol (Speech Intelligibility Screen; GOAT-Standard, Written, and Modified versions; Post Traumatic Amnesia Duration), the global outcome measures (R-GOSE and E-DRS-PI), and the AAB (CAP-COG and CRS-R [complete all levels for each subscale for training purposes]), and the other showing administration of all the measures in the CAB (RAVLT, Trail Making, WAIS-IV PSI, NIH Toolbox [cognitive measures only], the Participant/Surrogate Interview, BTACT, and all self-report measures). Two different videotapes (or more) are needed as more than one reviewer is necessary to certify the full battery. To avoid the need for IRB review, the battery should be administered to another member of the research team, rather than a participant. Data should be recorded on paper CRFs that can be found by navigating to Dropbox (Dropbox\1-TRACK TBI Doc Share\Outcomes Core\Outcomes Administrator Training\Outcomes training materials\Training CRF binders AAB and CAB). There are two separate binders, one each for the CAB and AAB. Select the appropriate binder with the most recent date appended to the file name. Make sure to open and print out the binders using **Adobe Reader** because Acrobat will remove certain updates that have been made to the document. For training purposes, the CAP_CogImp_Stimuli_FormAandB and CRF_Training_Stimuli_WAIS documents, located in the Outcome training materials folder on Dropbox, should be printed before recording the video as they contain the stimuli required to administer the WAIS and CAP measures. Helpful videos of the administration of all of the measures can be found on Dropbox (Dropbox\1-TRACK TBI Doc Share\Outcomes Core\Outcomes Administrator Training\Outcomes training materials\Example Battery Administrations for Certification).

After recording the administration of the batteries, scan your paper CRFs and send the electronic copies to Dr. Sabrina Taylor (Sabrina.Taylor@ucsf.edu). She will then send you a file request via Dropbox if you want to send you videos electronically.). **Do not post any videos containing test material to publically accessible websites such as YouTube.**

Certification of the Screening Protocol, Global Outcome Measures, and AAB measures will be conducted by:
Dr. Sabrina Taylor
University of California, San Francisco and Zuckerberg San Francisco General Hospital
1001 Potrero Ave
San Francisco, CA 94118
415-206-4457
sabrina.taylor@ucsf.edu

Certification of the CAB and BTACT will be conducted by:
Kim Boase
215-214th St SE
Bothell, WA 98021
206-744-8323
kboase@u.washington.edu

In addition, the C-SSRS and CRS-R each require review of videotaped training demonstrations (see specific instructions below), which must be completed prior to administration. Both the certificate of completion of training for the C-SSRS, and a copy of the answers to the CRS-R post-test, which should be completed following video review, should be emailed to Dr. Sabrina Taylor.

**Scheduling and Coordinating Follow-Up Appointments**

Consent to conduct follow-up outcome assessments was obtained at the time of study enrollment, so no additional consent is required. The nature and timing of the outcome assessment is based on the cohort to which the participant has been assigned (see Follow-up Schedule). Sites may wish to schedule all follow-up assessments when participants are first enrolled in the study, but will need to place reminder calls approximately 2 weeks in advance of each follow-up assessment date. It is also permissible to defer scheduling the 3, 6 and 12 month follow-ups at the time of enrollment; however, the 2 week follow-up should be scheduled at the time of enrollment or shortly thereafter. A minimum of two appointment reminders should be sent by mail, email, text, or telephone call, the second occurring 24 hours before the scheduled visit. The examiner needs to make all efforts to make sure that the participant will attend the follow-up session including working out the details of the logistics of travel, who will accompany the participant, even calling them the morning of the testing session. In cases of "no shows", the examiner should continue to attempt to reach the participant to perform the outcome evaluation until he/she is outside the pre-specified assessment window for that particular follow-up (see Follow-up Schedule). If the participant does not complete the follow-up assessment within the pre-specified assessment window of the target follow-up date, this follow-up assessment should be considered missed. However, under some circumstances, it may be appropriate for the site to collect the follow-up assessment data outside the window of the target follow-up date. The site should contact and get permission from the Executive Committee in order to collect this data. See the section "Schedule for Follow-up Assessments" above for the approved procedure. If it is possible to complete a measure by phone that could not be completed in person, an attempt should be made to do so. Telephone administration should be documented on the CRF. All points of contact should be documented. Participants should be informed that medications should be taken as prescribed on the day of the follow-up.

To avoid undue fatigue on the day of the scheduled assessment, every effort should be made to conduct the testing in the morning, before the participant engages in other required study visit activities (e.g. imaging, blood draws). If the outcome assessment battery cannot be completed prior to all other study visit activities, the examiner should ensure that the participant is given an adequate break, including snack or drink, before engaging or re-engaging the participant in the testing. See the Test Administration Order Table below for when the break should occur.

If the assessment battery cannot be completed on the scheduled day, testing should be completed within 3 days of the date it was initiated. *If it is not possible to complete an in-person assessment within the 3-day test completion window, the examiner should complete the Patient/Surrogate Interview and self-report measures by telephone.* If it is possible to complete the cognitive measures in-person outside the 3-day test completion window, the examiner should proceed with the assessment. The start and end dates of the assessment should be recorded on the CRF for each measure administered. If the battery cannot be completed within one day, the reason should be noted on the CRF.

**Conducting Follow-up Assessments in the Inpatient Setting**

All sites should set up a local process to coordinate outcome assessments for participants who are still in the inpatient setting at the time of the 2-week follow-up. The site PI should establish a procedure that enables the examiner to work with the attending physician and clinical staff to arrange and conduct the follow-up assessment in the ICU or on the ward. Before attempting to conduct the assessment, the examiner should speak with the appropriate clinical personnel to:

1. Obtain medical authorization to perform the assessment;
2. Establish whether there are contraindications for any portion of the assessment (e.g. application of deep pressure stimulation during administration of the Coma Recovery Scale- Revised in a participant with increased intracranial pressure;
3. Determine if there are precautions that need to be implemented (e.g. gown and mask);
4. Identify any sedating or paralytic medications that are on-board at the time of the assessment (and when they are administered);
5. Determine whether any other modifications to the examination are required.

**Test Selection and Time Limits**

The Screening Protocol should be used to determine whether the Abbreviated or Comprehensive Assessment Battery should be administered at the initial 2-week follow-up assessment. If the Abbreviated Assessment Battery is indicated, the examiner should proceed by following the steps detailed in the Flexible Outcome Assessment Workflow Algorithm shown below. If the Comprehensive Assessment Battery is indicated, the examiner should proceed by administering the measures in the order listed below in the section entitled, "CAB Test Administration Sequence."

Time limits and directions for test administration for individual measures should be strictly followed. Breaks should be provided as needed; however, participants should be discouraged from taking a break midway through a particular measure. Some participants may interrupt testing to engage in social conversation or become distracted in other ways. In these cases, the examiner should politely "re-orient" the participant back to the task at hand (e.g. "It is important to remain focused on the testing. Please try to avoid discussing other topics until the testing has been completed."). If the test order cannot be adhered to for any reason, the examiner should make note of the accommodations made.

## Establishing Rapport and Provision of General Instructions

The examiner should begin the assessment session by introducing him/herself by name and explaining his/her role. In addition, the examiner should describe the purpose of the testing, what the test(s) will be like, how long testing will take, and what the day's schedule will be, including when the participant may take breaks. The participant should be given an opportunity to ask questions and every effort should be made to place the individual at ease.

Since family members/close others may have difficulty avoiding helping the participant answer questions, it is generally better to test the participant alone. However, some participants may not tolerate having all family leave the room. In those cases, it is best to have family members sit behind the participant, out of the line of sight. Family members should be instructed to avoid making any comments during the assessment.

For administration of self-report measures (i.e. those included in the Post-concussive, Participation/Quality of Life and Psychological Health domains), both the examiner and the participant should have a copy of the questionnaire and/or record form in front of them. The examiner reads the instructions and presents the form to the patient. If the examiner has any doubt about the patient's reading level or ability to understand the content, the examiner should ask the participant to read and complete the first couple of items and make a determination. If it is clear the participant can read and understand the instructions, then allow the participant to complete the questionnaire on his/her own. The examiner should have a good idea about the cognitive capabilities of the subject based on the neuropsychological measures and the R-GOSE, which precede these measures. If the participant does need examiner assistance, then the examiner should read the items out loud and allow the participant to mark the form as independently as possible. The examiner may also record the responses for the subject if necessary. This procedure will help ensure that all items are presented appropriately while maintaining the confidentiality of the participant's responses.

Testing should not commence until the participant indicates readiness to begin.

## Ensuring Comprehension of Instructions

It is the examiner's responsibility to ensure that the participant understands the instructions before each test is started and that understanding is maintained throughout the test. Instructions may be repeated and clarifications provided as long as they reflect the standard instructions for each task. No new information, suggestions or hints should be provided at any time.

## Guidelines for Provision of Support and Feedback during Test Administration

During the assessment, if the participant requests feedback regarding his/her performance, only neutral feedback should be provided (e.g. "you are doing fine."). Good effort should be reinforced and, unless specified in the test instruction, no indication should be given that answers are right or wrong. Should the participant give more than one answer, ask that the "best" answer be provided, without cueing for a specific response. "Which one is it?" or "Choose one" can be useful prompts to get a participant to choose a single answer. If the participant gives an unclear or ambiguous response, request clarification rather than guessing at the intended response. Participants should be encouraged to give an answer even if they are unsure. "What's your best answer?" or "try" can be helpful prompts.

If the participant expresses or exhibits signs of frustration, or requests that testing be discontinued, the examiner should acknowledge the participant's concerns, and take note of any reported or expressed physical symptoms (e.g. pain, fatigue) that could interfere with test performance. If, in the examiner's

judgment, it may be possible to continue the testing, an attempt should be made to do so. The participant should not, under any circumstances, be pressed to continue the assessment as this may precipitate agitation, invalidate the test results and/or decrease the probability of returning for follow-up. Whether a participant is fatigued, frustrated or merely distracted, there is no one approach that will work with all participants, but the examiner should acknowledge the participant's concerns, consider the probability that the participant can be re-directed to the task and proceed accordingly.

### Use of Test Completion Codes

During the course of the assessment, the examiner is likely to encounter one or more of a wide range of problems that may interfere with test completion. A test is considered valid and complete when it is administered according to the test rules. In the event that a particular test cannot be initiated or completed, Test Completion Codes have been furnished to specify the reason(s) for non-completion. Test Completion Codes that indicate a measure cannot be completed due to cognitive/neurological limitations should not be applied to the Glasgow Outcome Scale-Extended, the Disability Rating Scale, the Participant/Surrogate Interview, or the Mayo-Portland Adaptability Inventory given that responses to questions included on these measures may be obtained from surrogates, family members or caretakers. Test Completion Codes are also not applicable to the Coma Recovery Scale- Revised as it is not possible to discern the reason for failure to respond to the items on this measure.

### Test Completion Codes

| | |
|---|---|
| **Test Attempted and completed** | |
| 1.0 | Test completed in full, in person- results valid |
| 1.1 | Non-standard administration – a measure normally requiring an oral response, allowed a written response, results valid |
| 1.2 | Non-standard administration –Other (specify):_____ |
| 1.3 | Test Completed, valid administration done over the phone |
| **Test Attempted but NOT completed** | |
| 2.1 | Test attempted but not completed due to cognitive/neurological reason |
| 2.2 | Test attempted but not completed due to non-neurological/physical reasons |
| 2.3 | Test attempted but not completed - participant cognitively intact enough to respond but poor effort, random responding, rote response, not cooperative, refusal, intoxication |
| 2.4 | Test attempted but not completed due to major problems with English language proficiency (and/or Spanish language proficiency if the site can also enroll Spanish speaking subjects) |
| 2.5 | Test attempted but not completed due to test interrupted by illness and test could not be completed later |
| 2.6 | Test attempted but not completed due to logistical reasons, other reasons – site specific |
| **Test not attempted** | |
| 3.1 | Test not attempted due to severity of cognitive/neurological deficits |
| 3.2 | Test not attempted due to non-neurological/physical reasons |
| 3.3 | Test not attempted - participant can respond appropriately but poor effort, not cooperative, refusal, intoxication |
| 3.4 | Test not attempted due to major problems with English language proficiency (and/or Spanish language proficiency if the site can also enroll Spanish speaking subjects) |
| 3.5 | Test not attempted due to participant illness and test could not be completed later |
| 3.6 | Test not attempted due to logistical reasons, other reasons – site specific |
| 4.0 | Test not attempted, completed or valid due to examiner error |
| 5.0 | Other (specify:_____) |

**Further Description of Test Completion Codes**

DEFINITION: A measure completion code is assigned to each of the measures administered to indicate the reason for missing data (if there is any), and to document any reasons why the validity of the data may be compromised. A Test Completion Code is also assigned to all measures that could not be administered unless the entire Outcomes milestone was missed. In this case, a Test Completion Code is assigned only to the Speech/GOAT/PTA assessment to indicate the reason for the Missed Milestone.

Measure completion code 1.0

Measure complete, scores valid: A code of 1.0 means that the measure was administered in person, under standardized conditions, the performance was complete according to the demands of the measure (including discontinuation criteria) and there is no reason to doubt the validity of the data. Test measures are scored and the value is entered into the database.

Measure completion codes 1.1 and 1.2

These completion codes indicate the test results are believed to be valid but test administration was not standard. For example, a measure completion code of 1.1 would be used if a participant had to write his or her responses on the recall trials of the RAVLT. A measure completion code of 1.2 would be used for other nonstandard circumstances involving changes to test administration or scoring rules. The situation should be described briefly in the text field. Test measures are scored and the value is entered into the database.

Measure completion code 1.3

Measure is complete, test administration and scoring are valid but measure was conducted in whole or partially over the phone instead of in person. The BTACT will also receive this measure completion code as long as it is complete and administered and scored according to the test rules. Test measures are scored and the value is entered into the database.

Measure completion codes 2.1 and 3.1

Measure attempted but not completed (code 2.1) or measure not attempted (code 3.1) due to cognitive/neurological-related limitations. These codes may be assigned if the participant is functioning at a cognitive level too low to be considered testable; if the instructions are provided but the participant does not understand them sufficiently to continue (comprehension impaired due to cognitive/neurological reasons); or if the test is started but must be discontinued because the participant is cognitively unable to finish or is unable to perceive test stimuli for reasons caused by the CNS disorder. These measure completion codes are intended for situations where cognitive/neurological deficits prevent an accurate score from being calculated. Test scores are therefore not entered.

These codes apply both to situations where the participant has been cognitively impaired continuously from the TBI onset to the assessment window, and to situations where the participant is cognitively impaired or has cognitively declined because of cerebral complications from any source (the TBI, a medical complication, or a later event affecting CNS function). Examples of the latter include: cognitive impairment due to infection from cranioplasty; status epilepticus; hydrocephalus; or re-bleed or delayed expansion of cerebral hematoma. Systemic problems that result in unresponsiveness or cognitive impairment, such as systemic infection or cardiac arrest are included to the extent that these conditions affect CNS functions.

Note that the Revised Glasgow Outcome Scale Extended (R-GOSE), Disability Rating Scale (DRS), Participant/Surrogate Interview, and Mayo-Portland Adaptability Inventory (MPAI) cannot be assigned a measure completion code of 2.1 or 3.1 because they can never be attempted but

"not completed" or "not attempted" due to cognitive/neurological-related limitations. If the participant is unable to take these tests due to cognitive/neurological-related limitations then they should be administered to the caregiver who is most informed about the participant. The examiner should attempt to determine which caregiver is the most knowledgeable about the participant. In most cases, this will be a family member, while in others, it will be a professional provider (e.g., nurse, therapist).

Measure Completion Codes 2.2 and 3.2

Measure attempted but not completed (code 2.2) or measure not attempted (code 3.2) due to non-neurological/physical reasons. Inability to take or complete the measure due to peripheral or non-neurological/physical reasons (e.g. both wrists broken so cannot do the Trail Making Test; jaw wired shut so cannot perform verbal tests; participant severely near-sighted and acuity non-corrected, so cannot do Symbol Search subtest).

Measure Completion Codes 2.3 and 3.3

Measure attempted but not completed (code 2.3) or measure not attempted (code 3.3). The participant is cognitively intact enough to respond but other factors affect performance such as: refusal to take or continue a measure; obvious poor effort, random or flippant responding, obvious response bias, lack of cooperation, intoxication, etc.

Measure Completion Codes 2.4 and 3.4

Test attempted but not completed (code 2.4) or test not attempted (code 3.4) due to major problems with English language proficiency (and/or Spanish language proficiency if the site can also enroll Spanish speaking subjects). For example, the participant does not speak or comprehend English or speaks and comprehends it but only with quite a lot of difficulty so the neuropsychological measures cannot be administered. Or the examiner is unable to find a translator or a knowledgeable informant that communicates in English in order to administer the other measures

Measure Completion Codes 2.5 and 3.5

Test attempted but not completed (code 2.5) or test not attempted (code 3.5) due to participant illness and the test could not be completed later.

Measure Completion Codes 2.6 and 3.6

Test attempted but not completed (code 2.6) or test not attempted (code 3.6) due to logistical reasons, other reasons – site specific. For example, due to insufficiency of staff or scheduling problems at the site the participant was not evaluated. This includes situations such as an examiner not being available to assess the participant.

Measure Completion Code 4.0

The test was not attempted, completed or valid due to examiner error. For example, the examiner forgot to administer or complete the measure, standardized instructions were not employed, required prompts were not given, inappropriate prompts were provided, timing rules violated, responses incorrectly recorded, or discontinue rules violated

Measure Completion Code 5.0

The test was not attempted or completed for another reason. Specify the reason on the line provided.

Data from the paper CRF's is housed in an electronic system called QuesGen. QuesGen forms have Form Completion Codes that are independent of Test Completion Codes. Specific guidance on how to

assign Test Completion Codes and Form Completion Codes is below and can be found at Dropbox \1-TRACK TBI  Doc Share\Outcomes Core\SOP\Test completion codes.

## Guidance on use of Form Completion Codes and Test Completion Code

| Situation | Form Completion Status | Test Completion Code Requirement |
|---|---|---|
| 1. No data entered in QuesGen | Not Started | No TCC required |
| 2. Data entry in QuesGen for a form is in process, but not complete | In Process | No TCC required |
| 3. Data entry in QuesGen for a form is complete; all errors have been addressed | Complete | TCC required |
| 4. Date entry in QuesGen for a form is complete but the form contains errors that need to be addressed. | Not Complete | TCC required |
| 5a. Missed Milestone visit on Patient Management – the battery has not been started. | SpeechGOAT CRF Incompletable - No Show. DO NOT select battery in "Battery Group Assigned" | TCC required on SpeechGOAT CRF only |
| 5b. CA Phone (2wk, 6M, 12M) or CA Partial on Patient Management -the Battery has been started, but was done via Phone when should have been In Person ***or*** battery was started but some forms were unable to be completed. | Select battery in "Battery Group Assigned". Marked missing measures as either *Incompletable – No Show* (if patient was no show without explanation or unable to make contact) or *Incompletable – Pt Factors* (if missed due to fatigue, refusal, illness, unable to access inpatient, etc.) | TCC required on each CRF (including those that were not started) |

| Example | Form Completion Code | Test Completion Code |
|---|---|---|
| 1. Unable to make contact with patient; patient failed to attend scheduled visit without explanation; coded as Missed Milestone in Patient Management | SpeechGOAT CRF Incompleteable-No Show; Do not assign Battery Group. No other Form Completion Codes required | SpeechGOAT CRF TCC=3.6 Test not attempted due to logistical reasons, other reasons – site specific. No other TCC's required |
| 2. Patient was too fatigued to complete the last few CRFs and did not want to continue | Incompletable – Pt Factors for all missed CRFs | for all missed CRFs TCC=3.3 Test not attempted subject can respond appropriately but poor effort, not cooperative, refusal, intoxication<br>Could also be 3.1 Test not attempted due to severity of cognitive/neurological reason if fatigue stems from TBI, unable to look at screen for Toolbox, etc |
| 3. Patient completed all forms over the phone for the 2 week visit due to being in rehab/back at work/sick | Symptoms surveys marked as Complete.<br>Cognitive measures marked as Incompleteable – Pt Factors. | Symptoms surveys marked as 1.3 Test completed over the phone.<br>Cognitive measures marked as Test not attempted 3.5/3.6 |
| 4. Patient completed half of the forms in person, but did not return in person to complete the rest and could not be reached to complete the rest of them over the phone | Forms that were administered marked as Complete.<br>Forms that were not able to be administered marked as Incompleteable – No Show. | Forms that were completed 1.0 Test completed in full.<br>Forms that were not able to be administered marked as 3.6 Test not attempted due to logistical reasons |
| Patient missed some questions on a single measure<br>5a. Due to refusal<br>5b. Due to examiner error | 5a. Complete +explain errors<br>5b. Complete +explain errors | 5a. 2.3 if skipped due to refusal<br>5b. 4.0 if missed due to examiner error<br>Add text to confounding var box |
| 6. Inpatient at 2 weeks and unable to access the patient due to their clinical care needs | SpeechGOAT CRF Incompleteable-Pt Factors | 3.6 not attempted due to logistical reasons, other reasons – site specific |
| 7. Inpatient at 2 weeks and able to complete some measures with surrogate, but unable to complete CRS/CAP with patient. | Forms that were done with surrogate marked as Complete.<br>Forms that were unable to be completed Incompletable-Pt Factors | Forms that were done with surrogate marked as 1.0<br>Forms that were not completed marked as 2.5/2.6/3.5/3.6.<br>TCC's 2.1/3.1 are likely not appropriate as the flexible battery allows the assessment of all patients regardless of cognitive impairment |

## General Guidelines for Scoring Responses

Responses should be scored based on the criteria provided in the instructions for each individual test. Where appropriate, verbal responses should be recorded verbatim and then converted to numerical form on the appropriate case report form. For example, on tests requiring word recall, the examiner should record each word the participant recalls during test administration. After the test is completed, the number of words recalled should be summed and the total recorded on the appropriate case report form. Remember to record responses on the paper CRF during test administration, and then to transfer the scores to the electronic CRF in QuesGen on the same day the assessment was conducted.

## Recording Factors that Confound Test Scores and Ratings

Anytime an examiner identifies a confounding factor that he or she believes may have influenced test administration, scoring and/or ratings (i.e. sedation, under the influence of illicit substances, effects of a new illness or injury, emotional lability, etc.), a narrative description of the confounding circumstance should be recorded on each applicable CRF in the section entitled, “Confounding issues not addressed by the Test Completion Codes” section. The examiner should ensure that the information provided contains sufficient detail. See also the additional test administration and scoring guidelines on p. 35.

## Battery Administration and Scoring Procedures

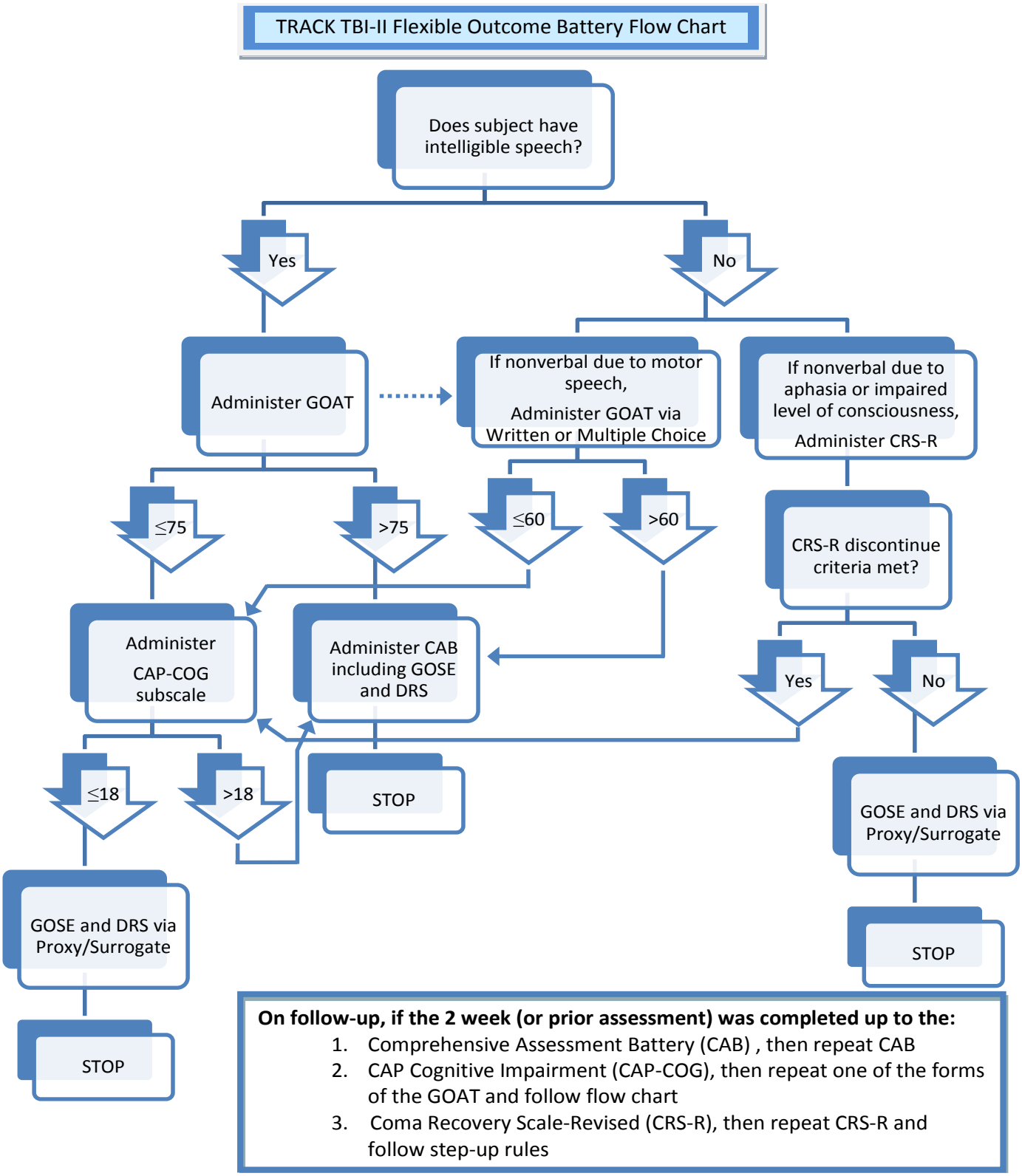
### Overview

In the sections below, directions are provided for administration and scoring of all measures included in the Flexible Outcome Assessment Battery. The battery is comprised of three parts- the Screening Protocol, the Abbreviated Assessment Battery and the Comprehensive Assessment Battery. For each of the 3 components of the battery, a brief description is provided for each measure included in the battery. This is followed by a key reference, information indicating when the measure is to be administered, the order of administration, instructions for standardized administration and scoring, and the name of the corresponding case report form.

The examiner begins the assessment by administering the screening protocol to determine whether the *Abbreviated (AAB)* or *Comprehensive Assessment Battery (CAB)* should be administered at the initial 2-week follow-up. The first step is to conduct a brief bedside test of speech intelligibility to ensure that the participant can speak intelligibly and at the sentence level. The speech intelligibility screen is followed by administration of the Galveston Orientation and Amnesia Test (GOAT), which is designed to detect post-traumatic amnesia (PTA). The results of these screening tests guide selection of either the Abbreviated or Comprehensive Assessment Battery.

## Flexible Outcome Assessment Flowchart

The Flexible Outcome Assessment Flowchart shown below illustrates the decision rules for selection of the appropriate test battery.



## Follow-up Assessments

The determination of which battery to administer during the 6 and 12-month in-person follow-ups depends on which battery was administered during the prior assessment:

- If the prior assessment was completed using the CAB, then the CAB should be repeated;
- If the prior assessment employed the AAB, and testing was discontinued following administration of the CAP-COG, then repeat one form of the GOAT and follow flowchart;
- If the prior assessment employed the AAB, and testing was discontinued following administration of the CRS-R, then the CRS-R should be repeated and the corresponding "step-up" rules followed.

## Test Administration Order

The measures included in the Flexible Outcome Assessment Battery should be administered in the order they appear in the table below. **Whenever possible, outcome assessment should be conducted before the neuroimaging and lab studies are performed.** Deferring the latter studies until after the outcome battery is completed will help prevent fatigue which may compromise test performance. If it is necessary to obtain the imaging and/or lab studies first, additional breaks may be necessary during test administration. *Before beginning the assessment, the examiner should also check the "CRF Time Line" tab after selecting the appropriate subject in QuesGen to determine if any data are missing from the Patient/Surrogate Interview that was completed at enrollment. Measures with missing data are color-coded in orange. The examiner should attempt to complete items with missing data during the interview portion of the assessment.*

| TRACK-TBI IN-PERSON OUTCOME ASSESSMENT TEST ADMINISTRATION ORDER |
|---|
| Screening Measures for Abbreviated and Comprehensive Batteries (5 - 7 min)<br>1. Assessment of Speech Intelligibility 2 min<br>2. GOAT 5 min<br>3. Post-traumatic amnesia (PTA) assessment 2 min |
| Abbreviated Battery (43 - 83 min)<br>4. Participant/Surrogate Interview (Living Situation, Follow-up Care, Return to Work) (15 min)<br>5. CRS-R 15 - 30 min *<br>6. CAP-COG 15 min *<br>7. R-GOSE 8 min<br>8. E-DRS-PI 5-15 min |
| Comprehensive Battery (58 min)<br>9. R-GOSE 8 min<br>10. RAVLT (5 learning trials, interference list with recall, immediate recall first list) 15 min<br>11. TMT (A&B) 5 min<br>12. WAIS-IV PSI (Coding and Symbol Search) 4 min<br>13. RPQ 6 min<br>14. SF-12 (Version) 3 min<br>15. RAVLT 20 Minute Delayed Recall 3 min<br>16. Qolibri-OS 2 min<br>17. PCL-5 6 min<br>18. BSI-18 6 min (if #17 ≥1, proceed to the C-SSRS) |
| 19. Participant/Surrogate Interview (Living Situation, Follow-up Care, Return to Work, Substance Abuse) 15 min |
| Break |

| |
|---|
| Comprehensive Battery (cont.) (61 - 71 min)<br>20. NIH Toolbox 30 min<br>21. MPAI4-PART 5 min<br>22. E-DRS-PI 5-15 min<br>23. PROMIS-PAIN (#22: Intensity and #23: Interference) 5 min<br>24. SWLS 3 min<br>25. ISI 3 min<br>26. PHQ-9 5 min (if #9 ≥1, proceed to the C-SSRS)<br>27. C-SSRS 5 min (*Only required if ≥1 on #9 [PHQ-9] or #17 [BSI-18]) |
| Additional Cognitive Measures by Telephone (20 - 25 min @ the 6-month follow-up)<br>BTACT |

*See the Workflow Algorithm Flowchart for when to administer the CRS-R and/or CAP-COG.

The test sequence is designed to ensure the fluency of the assessment battery, facilitate completion of the measures that are most instrumental to the study aims and, in the unusual event that a participant cannot complete the assessment, suggest optimal break points. While break points have been provided to optimize data capture, the importance of completing the full battery cannot be overstated. In each case, the examiner will need to exercise sound clinical judgment in deciding if and when battery discontinuation is necessary.

The test administration sequence always begins with the screening measures. If performance on the Screening measures indicates that the Abbreviated Battery should be administered, the CAP-COG and/or CRS-R are administered, followed by the R-GOSE and E-DRS-PI. The R-GOSE and E-DRS-PI are administered at the end of the Abbreviated Battery as prior completion of the CRS-R and/or CAP will facilitate obtaining functional outcome ratings on the global outcome measures. For example, the CRS-R profile will indicate whether the participant is in a vegetative state (R-GOSE Question #1). If performance on the Screening measures indicates that the Comprehensive Battery should be administered, the tests and interview items should be presented in the order shown in the Outcome Assessment Test Administration Order Table above. The examiner should begin by administering the first 10 measures listed (i.e. #9: R-GOSE through #18: BSI-18) followed by the Participant/Surrogate Interview. This portion of the assessment battery is estimated to run approximately 64 minutes. It is permissible to provide short breaks during this initial 64-minute assessment session, although the examiner should be mindful of the potential impact on the battery of breaking at a given point (e.g. extension of the prescribed delayed recall period on the RAVLT).

After the Participant/Surrogate Interview is completed, the examiner should provide the participant with a rest period if the participant needs a break. The length of the rest period will vary based on the participant's self-report and the examiner's observations. It is advisable to provide the participant with food and fluids during the extended break. During the break, the examiner should prepare the test environment for administration of the NIH Toolbox.

After the break, when the participant indicates he/she is ready to re-initiate testing, the examiner should administer the NIH Toolbox cognitive measures. After the Toolbox measures have been completed, the 7 self-report questionnaires should be administered (#21: MPAI4 through #26: PHQ-9). Note that the three questionnaires that include questions regarding suicidality have been placed at the end of the first (i.e. BSI-18) and second (i.e. PHQ-9, C-SSRS) testing sessions to avoid disrupting the other elements of the assessment. If the participant endorses ≥1 on #17 (BSI-18) or on #9 (PHQ-9) indicating suicidality ideation or behavior, the examiner should complete the current measure and proceed to administration of the C-SSRS for further assessment of risk. **Therefore, the C-SSRS will only be completed if the participant endorses ≥1 on #17 (BSI-18) or #9 (PHQ-9).** Ratings on the C-SSRS provide guidance as to how the examiner should address the suicidal ideation and/or behavior (see the Protocol for Managing Suicidal Ideation and Intent).

## Screening Measures for the Abbreviated and Comprehensive Assessment Batteries

*Assessment of Speech Intelligibility*

Description: The assessment of speech intelligibility measure is designed to determine if expressive speech or writing is intelligible at the sentence level. It can be administered either verbally or in written form.

When administered: The assessment of speech intelligibility should be administered at the 2, 6 and 12-month in-person follow-ups and by telephone at the 3-month follow-up. However, if the participant is deemed to have intelligible speech during any follow-up assessment, it is not necessary to repeat the assessment at the subsequent follow-ups. If the examiner suspects that there has been a decline in function since the prior assessment, the assessment of speech intelligibility should be re-administered to ensure that the participant has intelligible speech.

Order of Administration: The assessment of speech intelligibility is the first measure administered to all patients.

Form: Assessment of Speech Intelligibility (verbal or written)

Instructions: After the participant has been greeted and oriented to the assessment, the examiner should engage the participant in informal conversation to determine if expressive speech or writing is intelligible at the sentence level. Prompt the participant to repeat the sentence, **"In May, the apple trees blossom"** and record the response verbatim on the Speech Intelligibility CRF. If the participant's speech is intelligible, proceed to administration of the Standard GOAT.

If the participant's verbal output is not fully intelligible (i.e. one or more words cannot be understood), instruct the participant to write the following sentence, **"In May, the apple trees blossom"** on the lower half of the Speech Intelligibility CRF. Fold the page in half so the top half showing the verbal response is not visible to the participant. If the participant can respond in writing, proceed to administration of the Written GOAT.

In the event that the participant cannot respond verbally or in writing to the sentence prompt because of motor dysfunction (e.g. dysarthria, paralysis), proceed to administration of the Modified GOAT as indicated in the Workflow Algorithm and proceed with the assessment as indicated.

If the participant cannot respond verbally or in writing because of aphasia or disturbance in consciousness, the examiner should proceed to administration of the AAB. The AAB begins with administration of the Coma Recovery Scale- Revised (CRS-R) and, when the CRS-R discontinuation criteria (i.e. a score of 4 on the Auditory subscale [i.e. Consistent Command-Following] AND a score of 2 on the Communication subscale [i.e. Functional Yes-No Communication] AND a score of 3 on the Arousal subscale [i.e. Sustained Attention]), progresses to administration of the Cognitive Impairment Subscale of the Confusion Assessment Protocol (CAP-COG) (see Workflow Algorithm).

*Galveston Orientation and Amnesia Test (Standard GOAT)*

*Levin, O'Donnell, Grossman (1979)*

Description: The GOAT is a standardized assessment used to determine whether a participant is in post-traumatic amnesia (PTA). Post-traumatic amnesia is an early phase of TBI recovery during which the person with injury shows markedly impaired memory, confusion, fluctuation in performance (may be oriented on one exam but not on a later exam), disorientation, and other neurobehavioral signs and symptoms. GOAT questions assess orientation, memory for the first event that the participant can recall after the injury, (the period from the time of injury until the first new memory that can be consistently recalled is called the period of anterograde amnesia), and memory for the last event that the participant can recall from before the injury (the period from the injury back to last pre-injury memory is called the period of retrograde amnesia).

When Administered: The GOAT should be administered at the 2, 6 and 12-month in-person follow-ups and by telephone at the 3-month follow-up. However, if the participant scores above 75 during any follow-up assessment, it is not necessary to repeat the GOAT at the subsequent follow-ups. If the examiner suspects that there has been a decline in function since the prior assessment, the GOAT should be re-administered to ensure that the participant's score is >75 before going on to the CAB.

Order of Administration: The GOAT is administered following the Assessment of Speech Intelligibility (to participant's who are able to speak or write intelligibly at the sentence level).

Form: GOAT

Instructions: Inform the participant that you will ask a series of questions concerning their injury. Present the questions in the order they appear on the GOAT CRF and record the response verbatim. Participants are not allowed to self-cue during the GOAT so clocks, calendars, etc. should be out of sight and cannot be referred to. All answers should be recorded verbatim on the assessment form if possible. If the participant is unable to produce audible speech, it is permissible to accept sub-vocalized responses through lip-reading as long as the response is clearly intelligible. The GOAT has been adapted to accommodate participants who are nonverbal and/or unable to produce written responses. If the participant's verbal responses are difficult to understand due to motor speech impairment or inadequate voice volume, the Written GOAT should be administered. If the participant's speech *and* writing are unintelligible, the Modified GOAT (GOAT-M), which uses a multiple-choice response format, should be administered. See the instructions below for administration and scoring of the Written GOAT and the GOAT-M.

During administration of the GOAT, if the participant is slow to respond or does not respond at all, he/she can be cued to provide a response. For example, if the participant is unsure of the day of the month and is reluctant to answer, the examiner should encourage the participant to give his/her best answer. The participant cannot be cued with regard to content of answers, so if the participant is unsure regarding day of the week, the examiner CANNOT cue with something like, "We just finished the weekend, so what would that make today?"

Scoring Instructions: The GOAT score is calculated by subtracting the total number of error points from 100. Error points are scored for incorrect responses. A total of 108 error points may be awarded. In rare cases, participants may receive negative GOAT scores. Scoring for most questions on the GOAT is very straightforward. Error points for each incorrect response are indicated in parentheses on the case report form. The participant is asked his/her name (must give full name that he/she uses so Sarah Smith, not just Sarah), date of birth (must give month, date, and year), and city of residence (must give

correct town or city name, but not street address). The participant is asked the city of his/her current location and where he/she is (here one can prompt with “What kind of building is this?”). The person must state the type of location such as hospital, research center, etc. but does not have to give the full name of the location such as TIRR Memorial Hermann Hospital. Next the participant is asked the date of admission to the hospital. If the examination is occurring after hospital discharge, ask the participant the date of injury. Correct responses must include month, date, and year. The participant is asked how he/she got to his/her current location. For hospitalized persons, the correct response will usually be ambulance or air ambulance. For non-hospitalized persons, correct responses could include “my mother drove me,” I took a taxi, by train, etc.

Questions 4 and 5 ask the first post-injury memory and the last pre-injury memory, respectively. The examiner is almost certain not to know the correct answers to these questions, so answers are accepted if they are plausible. So, if for the first post-injury memory the participant says that he remembers his mother holding his hand, we would count this as correct unless we know for sure that the participant’s mother has not been to visit him. If the participant says that he went to a baseball game, but the examiner knows for certain that the participant has been in the hospital, this answer would be counted as incorrect. To avoid any error points, the participant must give some details in the response and, if there are no initial details, the participant should be cued to provide details if he/she can. So, if for the last pre-injury memory the participant says that he was on his way home from a bar, this answer is plausible and 5 error points would be avoided. To avoid the remaining 5 error points for question 5, the participant would have to add details (when prompted) such as that he was coming home from Harry’s Bar on Thursday after drinking with his bowling team. Again, these details are plausible and are accepted as correct as verification may be impossible.

The remaining questions concern time and date. The participant is asked to give the time and this should include whether it is daytime or nighttime. If the time given is within an hour window, 30 minutes before or 30 minutes after, no error points are assigned, so if the correct time is 10:06 in the morning, any time from 9:36 to 10:36 AM is accepted as correct. Each ½ hour off from the “free” window earns 1 error point. For example, 8:40 AM would earn 2 error points as this time falls within the 3rd 30-minute interval preceding the correct time (counting the “free” 30-minute interval between 9:36 and 10:06). To earn the maximum number of error points for this question, the participant must be 2 ½ or more hours off from the correct time in either direction. Therefore, any time earlier than 7:36 AM or any time later than 12:36 PM would earn the maximum 5 error points as these times are within or outside the 6th 30-minute interval following the correct time. The next question is day of the week. Each day off the correct day earns one error point. So a response of Monday earns 2 error points if the correct day is Wednesday. Note that both Sunday and Saturday would earn 3 error points since each is 3 days removed from Wednesday (Sunday is 3 days before and Saturday is 3 days after). The maximum error points for this item are 3. The next question is day of the month. Again, the examiner should count forward or backwards to determine how many days the date given is from the correct date. The maximum errors points for this item are 5. The next final two questions are month and year, which are scored similarly with maximum error points of 15 (5 points for each month off) and 30 (10 points for each year off), respectively.

Subtract the total error points from 100. If the total GOAT score on the standard administration of the GOAT is above 75, the examiner should proceed with administration of the CAB. If the total GOAT score is below 76, the Cognitive Impairment subscale of the Confusion Assessment Protocol (CAP-COG) should be administered and the examiner should refer to the Flexible Outcome Assessment Battery Workflow for further guidance on test administration. After scoring is complete, redact the participant’s name and date of birth from the form using a black marker.

*Written Galveston Orientation and Amnesia Test (Written GOAT)*

Description: The Written GOAT is used when the examiner believes the participant is able to comprehend the GOAT questions but is unable to communicate due to impairments in motor speech (dysarthria) or voice volume (hypophonia). The Written GOAT uses a written response format to accommodate problems related to restricted oral movement (e.g. jaw wiring, casting, splinting) and/or speech fluency (dysarthria). The Written GOAT is comprised of questions 1-3 and 6-10 on the Standard GOAT. Questions 4 (i.e. first event recalled after injury) and 5 (i.e. last event recalled before injury) are omitted as written responses cannot be compared directly to spoken language.

When Administered: If responses cannot be obtained verbally on the Standard GOAT.

Form: Written GOAT. Note that this is a 2-page form. The examiner should ensure that page 2 of the record sheet is not visible to the participant during completion of page 1.

Instructions: If the participant is unable to verbalize intelligibly on the Speech Intelligibility Screen due to disturbance in motor speech (e.g. dysarthria), voice volume (i.e. hypophonia) or injury to the face or jaw, but is able to write legibly, the written version of the GOAT should be administered. The examiner should read the questions aloud and instruct the participant to write his/her responses on the CRF for the Written GOAT. If the score on the Written GOAT is above 60, the CAB should be administered next, allowing the participant to write or select responses by pointing. If the Written GOAT score is below 61, the Cognitive Impairment subscale of the Confusion Assessment Protocol (CAP-COG) should be administered, allowing the participant to write or select responses non-verbally (e.g. pointing, head-nodding). If the CAP-COG score is above 18, the examiner should administer the CAB, instructing the participant to write or point to the appropriate response. Test completion codes should be used for tests that cannot be completed.

Scoring Instructions: Though the Written GOAT is a written version of the Standard GOAT, the Written GOAT omits questions 4 and 5 (20 total error points possible). Therefore, the maximum number of error points that can be obtained on the Written GOAT are 88, so the cut-off for impairment is $\leq$ 60 on the Written GOAT. Use the Standard GOAT form to determine the number of error points to award for each question that is also on the Written GOAT form. Error points are subtracted from 80 to obtain the Written GOAT score. After the participant completes the Written GOAT form, fill in the error points for each item in the space provided on the CRF. After scoring is complete, redact the participant's name and date of birth from the form using a black marker.

*Modified Galveston Orientation and Amnesia Test (GOAT-M)*

***Note: A personalized CRF must be created by the examiner before the GOAT-M can be administered (see instructions below in bold font).***

Description: The Modified GOAT is used when the examiner believes the participant is able to comprehend the GOAT questions but is unable to communicate due to impairments in verbal *and* written expression. The GOAT-M uses a multiple-choice response format to accommodate problems related to restricted oral and limb movement (e.g. jaw wiring, casting, splinting), weakness, dyspraxia and word-finding. Like the Written GOAT, the GOAT-M omits questions 4 (i.e. first event recalled after injury) and 5 (i.e. last event recalled before injury). The maximum number of error points that can be obtained on the GOAT-M are 88, therefore, the cut-off for impairment is $\leq$60 because the GOAT-M omits questions 4 and 5 (which total 20 error points).

When Administered: After demonstrating that responses cannot be obtained verbally on the standard GOAT, or in writing on the Written GOAT.

Form: GOAT-M. There are 3 alternate forms. Administer Version 1 the first time the GOAT-M is required, Version 2 the second time and Version 3 the third time. If a fourth administration is required, Version 1 should be repeated. Versions are not assigned to specific follow-ups as the GOAT-M is administered only when necessary.

Instructions: After the examiner determines that the multiple-choice version of the GOAT is required, the examiner must create a personalized GOAT-M CRF. The examiner will need to step away from the participant for a few minutes to create the CRF. To do so, the examiner will need to download TWO documents. The examiner should first download the Mayo procedure form on how to fill out the GOAT-M form from Dropbox (Dropbox\1-TRACK TBI Doc share\Outcomes Core\Assessments\ Administration and Scoring Guidelines\Modified GOAT procedure_Mayo). The examiner should also download the appropriate GOAT-M CRF template from Dropbox (Dropbox\1-TRACK TBI Doc Share\Outcomes Core\ Assessments\Record forms and Questionnaires\GOAT), and fill-in the blank items with the appropriate foil and personally-correct responses. The CRF template includes pre-filled choices for each item, however, for items 1 (name), 2 (date of birth), 3 (city of residence), 4 (current location), 5 (city hospital is located in), 6 (date of admission), and 13 (year), the examiner must add the answer to the record sheet that is correct for that particular participant. The personalized answer should be typed into the form, not written, so that it is indistinguishable from the alternative choices. For example, for question 1 (i.e. what is your name?), the examiner should type the participant's actual name on the blank line on the record form so that it appears with the three other incorrect names that appear on the form. For some items, only the correct answer needs to be added, for others, all 4 choices need to be added (e.g. day of the week). The Mayo Procedure Form explains in detail how to fill out these four answer choices for questions 8 (current time of day), 10 (day of the week), 11 (day of the month), and 12 (month) with the actual answers and the other possible choices.

The examiner should read each question and answer on the GOAT-M form aloud, pointing to the 4 choices on the record form that correspond to the answers of the question asked and instruct the participant to circle, point, or nod their head to indicate the correct answer. It is permissible to re-read the question, if requested. If the score on the GOAT-M is above 60, the CAB should be administered, allowing the participant to select responses non-verbally (e.g. pointing, head-nodding). Test Completion Codes should be used accordingly for tests that cannot be completed. For example, the Rey Auditory Verbal Learning Test cannot be administered via multiple choice. If the GOAT-M score is below 61, the examination should be discontinued as the CAP-COG cannot be administered in full via multiple choice.

Scoring Instructions: The GOAT-M is scored in the same way as the Written GOAT. Use the Standard GOAT form to determine the distribution of error points that can be awarded for each question on the GOAT-M form. Total error points that can be awarded are 88. *Note that the patient's answer to Question #9 regarding am/pm time of day will be used to score Question #8 as in the Standard and Written GOAT versions.* After the participant completes the GOAT-M form, fill in the error points for each item in the space provided on the CRF. Error points are subtracted from 80 to obtain the GOAT-M score. Note, for questions 6-10, incorrect responses result in the maximum number of error points possible for each of these questions. After scoring is complete, redact the participant's name and date of birth from the form using a black marker.

*Assessment of post-traumatic amnesia (PTA) duration*

Description: The assessment of post-traumatic amnesia (PTA) duration is conducted interview-style, and is designed to discern if the patient experienced a period of PTA after injury and how long this period lasted.

When Administered: The assessment of PTA duration will be administered to all participants only once during either the 2 week, 3 month, 6 month or 12 month follow-up. This assessment will be administered only when the patient scores > 75 on the Standard GOAT (or > 60 on the Written or Modified GOAT). If the GOAT score is ≤ 75 at the 2 week assessment, wait until the 3 month telephone follow-up and reassess with the GOAT. If the patient scores ≤ 75 on the GOAT at the 3 month assessment, wait until the 6 month follow-up and reassess with the GOAT. If the patient scores ≤ 75 on the GOAT at the 6 month assessment, wait until the 12 month follow-up and reassess with the GOAT. If the patient scores ≤ 75 on the GOAT at the 12 month assessment, do not administer the Assessment of PTA. While this measure is considered one of the "Screening Measures", the results of this test will not determine which battery the participant will be administered. See the instructions within the applicable GOAT version (i.e. Standard, Written, or Modified) section to determine whether to administer the AAB or CAB.

Order of Administration: The assessment of PTA duration is administered following the GOAT.

Form: Assessment of Post-Traumatic Amnesia (PTA) Duration

Instructions: Read the following instructions to the participant: **"Now I'm going to ask you a few more questions about your memories after your injury. After a brain injury, there may be a period of time in which an injured person can't remember anything because they were dazed or unconscious. Then, they may remember bits and pieces of events, which are called islands of memory, before their continuous memory for day-to-day events returns. Following your injury, was there a period of time in which you could not remember anything at all, or only bits and pieces of events?"**

If the participant indicates that there was not a period of time in which they could not remember, record an answer of "Immediate" on the CRF. If the participant indicates that there was a period of time in which they could not remember ask: **"Can you estimate about how long you think it was between your injury and the time when you felt like you started remembering things continuously again? This period of time may be as little as a few minutes to days or even weeks."**

If the subject confuses emergence from PTA with being able to remember things normally as usual, say, **"This does not mean that your memory is completely back to normal but rather that you started remembering things on a more continuous basis."** You can ask questions as necessary to prompt the participant. Some example questions are: What was the first thing after the event that you remember? Where were you? Who was there? What was going on around you? Tell me more about what happened next? Do you remember when the medics got to the scene? Do you remember the ambulance ride? Do you remember your time in the emergency department?

Control instructions: In the second sentence of the instructions, drop the word, "brain" so the sentence reads: "**After an injury, there may be a period of time in which an injured person can't remember anything because they were dazed or unconscious**." Administer the remaining instructions as originally worded. The examiner should ensure that control subjects have not experienced PTA, either as a result of their original injury (subjects who experienced PTA should have been captured on enrollment), or due to a brain injury that occurred after enrollment (i.e. within the first two weeks of the

study). If a control subject is discovered to have PTA or RA, the examiner should mark the subject's record in QuesGen accordingly. These subjects will remain in the study as per original protocol.

Scoring Instructions: Record the amount of time for duration of PTA in the number of minutes, days, or hours in the areas provided, or write in an amount of time next to "other" on the CRF if the participant indicates that he/she was in PTA longer.

**Global Outcome Measures**

Functional outcome ratings should be obtained on all participants, regardless of which battery is administered, using the Revised Glasgow Outcome Scale- Extended (R-GOSE) and the Extended Disability Rating Scale- Post-acute Interview (E-DRS-PI). These are the primary outcome measures for the TRACK TBI study.

For participants who receive the AAB, a surrogate should be interviewed to obtain the R-GOSE and E-DRS-PI ratings. The surrogate may be a family member, friend, or healthcare professional. The examiner should ensure that the surrogate is well-acquainted with the participant's current and past history. In some cases, it may be necessary to consult multiple sources to obtain the most reliable information. Participants who undergo the CAB should be interviewed directly. When it is not possible to interview the patient directly during administration of the CAB, a surrogate interviewee should be identified.

The R-GOSE and E-DRS-PI are both measures of functional status that utilize a structured interview to obtain information about an individual's actual or perceived ability to carry out basic self-care and activities of daily living. Because these two measures share similar content and include some similarly-worded questions, the examiner has some latitude in the manner in which the R-GOSE and E-DRS-PI questions are asked. Overlapping content is most apparent on items designed to rate general level of function (i.e. how well one is able to function on a daily basis, accounting for brain injury-related physical, cognitive, social and emotional problems) and capacity to work. In particular, E-DRS-PI questions 7 (i.e. Level of Functioning) and 8 (i.e. Employability) overlap with R-GOSE content. In view of the overlap, it may be unnecessary to ask one or more of the questions included on the E-DRS-PI. By the time the examiner is ready to administer the E-DRS-PI interview, he/she will have had the benefit of having obtained the respondent's answers to all of the R-GOSE questions. Depending on which questions the examiner chooses to ask during the R-GOSE interview, it may be possible to either, a) fill in the answers to E-DRS-PI questions 7 and/or 8 using the information acquired during the R-GOSE interview or b) ask a subset of the E-DRS-PI questions to supplement the information already obtained during administration of the R-GOSE. For example, item 7.1 on the E-DRS-PI asks, "Do you function completely independently? That is, you do not require any physical assistance, supervision, equipment, devices, or reminders for cognitive, social, behavioral, emotional, and physical function." If the examiner has already determined that the subject does not require any type of assistance based on responses to R-GOSE questions 2a (i.e. Independence in the Home) and 3a (i.e. Independence Outside the Home), item 7.1 can be answered "Yes" and scored "0." If the examiner is uncertain about whether an E-DRS-PI item can be scored using responses obtained during the R-GOSE interview, the E-DRS-PI item should be administered.

*Revised Glasgow Outcome Scale- Extended (R-GOSE)*

*J. T. Lindsay Wilson, Laura E. L. Pettigrew, Graham M. Teasdale. Structured Interviews for the Glasgow Outcome Scale and the Extended Glasgow Outcome Scale: Guidelines for Their Use. Journal of Neurotrauma Volume 15, Number 8, 1998; 573-585.*

Description: The Revised Glasgow Outcome Scale Extended (R-GOSE) is a measure of disability and handicap intended for use following head injury. It was developed specifically to meet the aims of the TRACK-TBI study and is based on the GOSE structured interview (Wilson et al. 1998). Unlike the GOSE, which does not distinguish between disability related to the brain injury and disability related to peripheral injuries sustained in the same incident, the R-GOSE assesses the impact of both non-CNS injuries (i.e. peripheral injuries) and the brain injury separately. As a result, two scores are obtained: an 'All' rating which reflects the participant's change in level of dependence as a function of peripheral and brain injuries combined, and a 'TBI' rating that removes the impact of the peripheral injuries leaving a disability rating that reflects only the TBI.

Like the GOSE, the R-GOSE subdivides the upper three categories of the original Glasgow Outcome Scale (GOS), severe disability, moderate disability and good recovery, into an eight-category scale: dead, vegetative state, lower severe disability, upper severe disability, lower moderate disability, upper moderate disability, lower good recovery, and upper good recovery to provide more detailed assessment of the functional effects of the injury. The instructions below were developed for the R-GOSE.

When Administered: The R-GOSE should be administered in person at 2 weeks, 3 months (by telephone), 6 months and 12 months post-injury to participants stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts. For the Brief Assessment cohort, the R-GOSE should be administered by telephone at 2 weeks, 3 months, 6 months, and 12 months. It is the only outcome measure that is to be administered to the Brief Assessment cohort.

Order of Administration**:** The R-GOSE is the primary outcome measure for the study. Thus, all participants enrolled should receive R-GOSE ratings. For participants who undergo the AAB, the R-GOSE should be administered after the CRS-R and/or CAP-COG. For participants who undergo the CAB, the R-GOSE is the first measure administered.

Form: R-GOSE

Instructions: The R-GOSE should be administered via structured interview (see instructions: Dropbox\1-TRACK TBI Doc Share\Outcomes Core\Assessments\Record Forms and Questionnaires\Revised GOSE\The_GOSE_revised_instructions8272014 tc.docx) directly to participants who are able to verbalize intelligibly *and* attain a score >75 on the GOAT (or >61 on the Modified GOAT). If the participant does not meet these criteria, a close relative or caregiver should be interviewed and the type of respondent (i.e. participant, relative/caretaker) marked on the CRF. The examiner should consult the additional scoring guidelines detailed below before rating each item and assigning an outcome category. Depending on the answers to earlier questions relevant to a particular item, later questions are skipped. *All items on the R-GOSE should be administered, even after a final rating is established (except those that are specifically skipped due to the established skip rules)*. The only exception to this rule occurs when the surrogate is being interviewed and answers "no" to question #1, indicating that the participant is in a "vegetative state." Completion of all items above the "VS" category will enable a more thorough analysis of functional status.

Remember the intent of the measure is to determine how disabled this individual is. It is intended to be given as an interview. You will need to ask additional questions to get the information you need. The questions do not have to be asked exactly as is but they need to keep intact the intent of the area being queried. Always go with the best source of information. In most cases it will be the participant but if something seems not quite right based on your observations and things you've learned from nursing or family members you may need to enlist the input of other sources as well. *We want the most accurate information*. In some cases, this means obtaining additional input from significant others, and in other situations, from clinical staff.

*Q1. Vegetative State (VS)*.

This question is intended for those patients who are untestable because of disturbance in consciousness, inability to follow commands or other forms of severe cognitive disturbance. It's OK to skip this question for participants who undergo the CAB. If the participant is unable to obey commands or say words for some other reason, for example, because they are severely demented, then they are not in the VS. "Any words" includes repetition of a simple word such as "No". A person able to communicate using a code would no longer be in the VS. Patients who demonstrate sustained visual pursuit (i.e. tracking) are not in the VS. In the VS, the eyes may fleetingly turn to follow or fixate on an object; however, neither sustained visual fixation nor sustained pursuit occurs in the VS. Thus, the participant who demonstrates only visual pursuit would fall in the lower severe category of the R-GOSE (see below for more information on the lower severe category). The diagnostic criteria for VS described in the guidelines published by the Aspen Workgroup in the USA and the Royal College of Physicians in the UK have been incorporated into the CRS-R so the examiner should review these results before answering Question #1.

*Q2. Independence in the Home*

*Q2a*. Dependency may be caused by physical impairment, but it is also often due to mental changes. People may require actual assistance with activities of daily living, they may need prompting or reminding to do things, or they may need someone with them to supervise them because they would be unsafe otherwise. In all these cases, they are dependent. However, many people receive assistance, but do not absolutely depend on it. This care or protection that is given by others should be distinguished from dependency: the person may well benefit from this help and may well have a real need for it, but such care does not mean that they are dependent in the sense required here. A difficulty may arise if an activity was not normally carried out before the injury. For example, many men have little practical involvement in domestic matters and quite often will not usually prepare meals for themselves. In this case, it is sufficient that the person could, if the necessity arose, prepare food, even if this would be in a simple fashion. Examples of minor domestic crises: what you do if ... a glass gets dropped and broken, a tap is left running, a light goes out, it begins to get cold, a stranger comes to the door...The person should be able to use the phone to report problems or call for help.

The intent of this question is to find out if the participant can be left alone for a 24 hour period. After asking the question, give them examples (some are listed on the test form). Consider issues of safety and being able to meet daily needs. Will they get dressed, will they eat, are they safe (won't burn the house down), can they handle with good judgment small emergencies? They won't wander off and become lost if unsupervised. Will they take prescribed medications correctly?

If they say they need some help during the day, ask them what kind of help they are getting. I make notes of these things. Sometimes the help they are getting is for things like showering, laundry,

household tasks. These do not count for this item. They do not need to be done on a daily basis and do not impact the safety and well-being of the participant.

*Q2b.* The participant is considered to be in the lower category of severe disability if they cannot be left alone for 8 h. This limit implies that a relative who is caring for them cannot work. If it is necessary to establish a time limit, it can be helpful to ask "what is the maximum amount of time they can be left alone?"

Also, keep in mind, this is help they NEED. They may be getting help but they really don't need it any longer. This may be a judgment call.

*Q3. Shopping & Q4. Travel: Independence Outside the Home*

Independence outside the home requires ability to plan, to take care of money, and behave appropriately in public. It must be established if the person is actually capable of carrying out these activities, rather than whether they do or not. This doesn't need to be a major shopping trip. Can they buy a loaf of bread at the local 7-11? Can they find what they want, handle money for a simple transaction, behave in an appropriate manner, etc.

Travel – they don't have to be driving but need to be able to make arrangements to get somewhere. Can they call a taxi, call a friend, tell them where they need to go etc.

*Q5. Work*

Work is only used as an indicator of outcome if the person was working or actively seeking work before the injury, or if they were studying.

*Q5a.* "Work" refers to jobs that are paid at a reasonable rate and which, in principle at least, are open to others. "Reduced capacity for work" Any of the following indicate reduced capacity for work: (a) change in level of skill or responsibility required; (b) change from full-time to part-time working; (c) special allowances made by employer (e.g. increased supervision at work); and (d) change from steady to casual employment (i.e. no longer able to hold steady job). Note that sometimes change in employment status may be unrelated to head injury, e.g. due to end of contract, retirement, or redundancy. Such changes do not indicate a reduced capacity for work.

Work – if they say they are back to work check to see if they have returned to their same number of hours, same work load. Are there any changes in what they are able to do? Has a co-worker taken on some of their responsibilities? A participant may say they are ready to go back to work, however, if they have not been released by their doctor we consider them not ready to return.

If the participant is a student it applies in a similar fashion. Have they returned to school? Are they taking the same course load? Are they able to keep up to previous expectations? Not failing classes etc.

In some cases work may not be applicable (retired for instance). In this case, this item should not be used in the final outcome determination. Social and leisure can be used instead to assess this level of disability.

According to Dr. Wilson's article, work is supposed to be paid, competitive employment. Some people may say they aren't working now and were not working before the injury. Unless they are retired, disabled (pre-injury), a student or a homemaker we would still think of them in terms of being a worker so we can rate a change in this area but it would be based on their 'guesstimate' of what they would be able to do. You might ask questions like '*do you think you would be able to work at the same capacity*

*as before', 'do you think there would be problems related to the injury that would cause difficulty in your ability to work up to your previous capacity'.* Again, look for change. There could be other reasons that might take someone out of the workforce so don't use this as an exhaustive list.

If the person tells you he was not working or seeking employment prior to the injury but he was a student, ask the work section this way:

*Are you currently able to return to school at your previous capacity? Are you attending school for the same number of hours as before your injury? Are you taking the same course load? Are you able to keep up to previous expectations, not failing classes?*

If the person was neither working, seeking employment or a student before the injury (e.g. homemaker only or retired) than this category can be skipped since it cannot be used to determine the R-GOSE score.

*Students Q5a.* If the person was a student before injury, then "study" can be substituted for "work". Students should be able to return to their previous course and not have noted adverse effects on their ability to study. If someone has been absent from college because of injury, then there may be some disruption caused by the absence itself, and this needs to be discounted when considering if the person has problems due to the head injury. Examples of problems which indicate reduced capacity for study: (a) increased difficulties in studying (e.g. needing to spend much more time than before); (b) unaccustomed problems with progress (e.g. failing examinations); and (c) revised program of study because of problems (e.g. studying for a lesser qualification).

*Q5b (R-GOSE only).* "Noncompetitive work" includes work done voluntarily, jobs that are specifically designated for disabled people, and work in sheltered workshops. Normally, ability to work is indicative of independence; however, occasionally, someone in the upper severe disability range may be working in a sheltered workshop.

*Students Q5b.* (a) If the student has a reduced capacity for study but is still studying, then they are Upper Moderate disability; and (b) if the student is currently unable to study, then they are Lower Moderate disability.

*Q6. Social & Leisure Activities*

Social and leisure activities will vary depending on the age and background of the participant. Representative social & leisure activities reported by patients in Glasgow include the following: (a) participating in sport, e.g. football, swimming, etc., (b) attending sporting events as a spectator, (c) going walking, (d) going to a club or pub, and (e) visiting friends. Some leisure activities are seasonal, and one must be careful to exclude changes in activities that are simply due to this factor. Typical problems that may interfere with social and leisure activities: lack of motivation or initiative, avoidance of social involvement, physical problems such as loss of mobility, cognitive problems such as poor concentration, problems such as poor temper control or impatience.

If they say they have returned to their activities ask them if they participate at the same level of intensity, same frequency. Many patients may have returned to their activities but don't have the stamina to sustain their previous level of activity. Start out by asking them what activities they participated in before their injury then ask what they are doing now. Usually this makes it fairly clear. Everyone has something that can fall into this category. It does not have to be outside the home. Can be visiting with friends, going out to lunch, walking, gardening, reading, video games, etc.

*Q6b. Extent of restriction.* If it is necessary to question in detail, then ask the person how often they participated in social and leisure activities outside the home before the injury (i.e. how many occasions per week) and how often they participate now. Measuring extent of participation is in terms of occasions per week emphasizes a quantifiable aspect of social and leisure activities. Sometimes, quality of participation is affected by the head injury; for example, the person may become a spectator in a sport rather than an active participant. However, changes such as this are very difficult to quantify and can reflect the specially demanding nature of some sports. Thus, for the sake of simplicity, it is the fact of participation that is rated in the interview. Experience suggests that the main effect of head injury on social and leisure activities tends to be withdrawal from activities that involve social interaction: the simple approach adopted here is sensitive to such changes.

*Q6c.* Participating regularly in social and leisure activities means participating in at least one activity outside the home each week.

*Q7. Family & Friendships*

The question is specifically aimed at alterations in relationships as a result of head injury. The presence of a reported change in personality is not of itself sufficient to warrant classifying the person as moderately disabled - the change must be having an adverse impact on family and friendships.

This question isn't intended to find out if they are irritable, etc. – these examples are mentioned as areas of difficulty that can impact relationships. We want to know if their relationships are strained and if so how much.

*Q7b.* Extent of disruption or strain. The following definitions apply: (a) Occasional – Some problems since injury, but less than once a week and not causing continuous strain. For example, occasional bad temper, but things blow over. (b) Frequent - Problems at least weekly, strain on relationships, but regarded as tolerable. For example, temper outbursts at least once a week resulting in modification of closeness of relationships. (c) Constant daily problems - Breakdown or threatened breakdown of relationship within family or friendship; problems regarded as intolerable. If a family has become very withdrawn and socially isolated as a result of injury, then this also represents constant disruption.

*Q8. Return to normal life*

*Q8a*. The list of problems here includes those described as the post-concussion syndrome. The problems are impairments; in order to cause disability they must impinge on functioning in everyday life. Similar problems are reported in the general population: it is thus important to establish that the problems have developed since injury.

Other difficulties/symptoms – Give some examples of these – several are listed on the test form.

*When you ask if these problems were present before and the answer is 'yes' (to headaches for example); if these headaches are worse now or more frequent, mark the pre-question as a 'no'.

Control instructions: The examiner will obtain only one score for the R-GOSE (v. "All" and "Brain only" scores). Because subjects in the ortho control group cannot have any evidence of brain injury to be eligible for enrollment, the obtained score should reflect only the impact of peripheral injuries on functional status.

- For question "A" under Peripheral Injuries," the sentence has been modified to read: "Did you sustain any peripheral injuries (e.g., fractured limbs, spinal cord injury, complications from other system surgeries, etc.)? Record all peripheral injuries reported in section A1.

- Do not administer question #1: “Is the head injured person able to obey simple commands or say any words?”
- Do not administer any questions that have been “grayed out” on the paper CRF. The parts of the questions that are grayed out were designed to separate out the impact of the peripheral injuries from the TBI, and do not pertain to control subjects.
- Indicate on the electronic CRFs in QuesGen that the patient is a Control Subject. The order of questions and response dropdown menus will be the same. The singular response options that are grayed out on the paper form will still appear in the eCRF dropdown on QuesGen, but these responses should not be selected.

Scoring instructions: The final rating is the lowest ranking on any item that constitutes a change (gets worse) from before the injury. For example, if they are not working now but were not considered a worker before the injury (retired) you wouldn’t want to rate the interview on this item. Or if they have family discord now but it was the same before – don’t base the ranking on this item. More specifically, you ask question 7a, ‘have there been psychological problems which have resulted in ongoing family disruption or disruption to friendships?’ The person says ‘yes’. Then you ask question 7b to determine the extent of the disruption or strain. Then you ask question 7c, ‘were there problems with family or friends before the injury?’ If the person says ‘yes’ you must ask more questions to find out if the problem they had before the injury is really the same as it is now. You will want to find out if the problem is worse, affects more people or if anything about it has gotten worse even if some parts are the same. If anything is worse than before the injury the question 7c = no. If the situation is the same as before (question 7c = yes) then the score in this category cannot be used when calculating the total score.

*Expanded Disability Rating Scale- Post-acute Interview (E-DRS-PI)*

Description: The E-DRS-PI measures the degree of disability experienced by an individual with a history of TBI using a structured interview. The answers to the interview questions are designed to guide the ratings of the items represented on the E-DRS-PI. The higher the total score, the greater the degree of disability. The interview is comprised of a series of multiple-choice questions that pertain to neurologic function, self-care and vocational activities. Depending on the answers to earlier questions relevant to a particular item, later questions are skipped. The total score is computed through use of an algorithm. For purposes of the TRACK-TBI study, examiners will simply enter the rating for each item on the paper and electronic CRF and the total score will be calculated through QuesGen.

Separate versions of the E-DRS-PI questions have been provided for individuals with TBI and for caregivers. The first three items, "Eye Opening," "Communication Ability" and "Motor Response," are a slight modification of the Glasgow Coma Scale (Teasdale and Jennett, 1974), and reflect impairment ratings. For the Caregiver Form, all three of these questions are included. However, the items that ask about the status of eye-opening and motor functions have been omitted from the Survivor Form because both eye-opening and basic motor functions, including command following, have recovered in those who are able to respond directly to interview questions. This represents a modification of the published version of the E-DRS-PI interview and accompanying scoring algorithm. The scoring algorithm for the Caregiver form is identical to the Survivor form, but also includes scoring rules for Eye-Opening and Motor function taken from the original DRS. Only the orientation questions from the communication subscale of the original DRS are included in the E-DRS-PI, since communication in participants who are able to be interviewed directly has recovered to normal limits. Self-care ratings, Level of Functioning, and Employability questions are found on both the Caregiver and Survivor Forms. Self-care ratings (i.e. "Feeding," "Toileting" and "Grooming") reflect the level of disability caused by cognitive (not physical) problems. The "Level of Functioning" item considers the level of assistance required for daily activities and is based on the combination of *both* cognitive and physical impairments.

The "Employability" item captures the degree of autonomy an individual is expected to be able to perform at in the work setting, taking into account *both* cognitive and physical impairments. Unlike the original DRS, the E-DRS-PI provides a rating of actual current employment; however, the eCRF will automatically generate the score.

When Administered: The E-DRS-PI should be administered at the 2-week, 3-month (by telephone), 6-month and 12-month follow-ups to participants stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts. The E-DRS-PI is not administered to the Brief Assessment cohort.

Order of Administration: Administer the E-DRS-PI after the R-GOSE in the AAB, and after the MPAI and before PROMIS Pain Intensity in the CAB.

Form: There are two interview forms. The Survivor form is used when the participant is capable of responding to questions independently. The Caregiver form is used when the participant cannot answer the questions for either physical (e.g. jaw wired shut) or cognitive (e.g. in a confusional state) reasons and the examiner must rely on a surrogate. For participants who undergo the AAB, a caretaker should be interviewed and the Caregiver form used. Participants who undergo the CAB should be interviewed directly, unless they cannot do so for physical reasons.

Instructions: When possible, the E-DRS-PI should be completed by interviewing the participant directly. However, if the participant is unable to engage in the interview, the examiner should interview a surrogate who is knowledgeable about the participant's past and current history. The medical chart can also serve as a source of information. The examiner should record all sources of information on the case report form. To determine the subscale scores, the examiner should first determine whether the participant has any physical limitations. If there are none, then anything less than the ability for full functioning can be assumed to be due to cognitive deficits. Questions such as, "Does John need help to complete personal hygiene? Does John need someone else to help set up equipment (toothbrush and toothpaste, comb, shaver)? Does John need prompting to complete task or reminders, i.e. changing clothes? Does John indicate (i.e. squirming in his chair) that he needs to void?" will help scoring for cognitive ability. Note that the "Employability" item does not represent a rating of actual employment. This item refers to the overall cognitive and physical ability to be an employee, homemaker or student. The rating system reflects the participant's or caretaker's knowledge of *how and when* the activity should be performed. Ratings should be based on participant or caretaker observations made over the last 48-72 hours. When the examiner is unable to decide whether a particular item should receive the higher or lower of two scores, the higher score should be assigned. Specific DRS scoring guidelines are included in Dropbox (Dropbox\1-TRACK TBI Doc Share\Outcomes Core\Assessments\ Administration and Scoring Guidelines).

Control instructions: There are no modifications to the administration of the E-DRS-PI to controls. However, the Caregiver version should not be administered to control participants.

**Participant/Surrogate Interviews**

Description: The Interviews, like the Global Outcome Measures, are administered to all participants regardless of whether the Abbreviated or Comprehensive Assessment Battery is conducted. In most cases, when the participant screens into the AAB, it will be necessary to interview a surrogate instead of the participant as responses may be unreliable. The first of the Participant/Surrogate Interviews is the Preinjury Interview and is administered to all participants at the time of study enrollment to obtain pre-injury information (i.e. demographic information, pre-injury educational and employment histories, prior substance use, emotional and psychiatric difficulties, prior TBIs and other CNS disorders). The 2

week follow-up interview primarily collects information about the person since the injury (i.e. living situation, education, employment, substance use, symptoms, and satisfaction with support from others). The 3 month, 6 month, and 12 month follow-up interviews include some items from prior follow-ups as well as new questions pertaining to such topics as symptoms experienced (e.g. seizure) and treatment services received (e.g. PT, OT, ST) since injury.

When Administered: The Pre-Injury Interview is conducted by the study coordinator at the time of enrollment for all participants stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts (regardless of the battery administered). The 2-Week Interview is conducted by the outcome examiner at the 2 week assessment. It can be administered over the phone if, in the outcome examiner's judgment, sufficient rapport has not yet been developed to ask some of the more sensitive questions (e.g., substance abuse), the person is too stressed or in too much pain to do the interview comfortably. *Any items on the Pre-Injury Questionnaire that have not been completed at the time of the 2-week follow-up should be completed at that time.* The 3 (phone), 6, and 12 month Interviews should be conducted by the outcome examiner at the appropriate assessment times. Forms can be checked for completeness by clicking on the "CRF Time Line" tab after selecting the appropriate subject in QuesGen.

Order of Administration: In the AAB, the Participant/Surrogate Interview is the first measure obtained after the Screening Protocol followed by the CRS-R and/or the CAP-COG (follow the Workflow Algorithm for proper administration). In the CAB, the Participant/Surrogate Interview should be conducted after administration of the BSI-18 and before the NIH Toolbox Cognitive Battery.

Form: Pre-Injury, 2-Week, 3-Month, 6-Month, or 12-Month Participant/Surrogate Interview Forms. See the table below for more information as to the types of questions included in the Interview at each follow-up time point.

| Pre-Injury | 2 Weeks | 3 Months | 6 Months | 12 Months |
|---|---|---|---|---|
| Socioeconomics | Living Situation | Living Situation | Living Situation | Living Situation |
| Health economics | Employment/School Status | Employment/School Status | Employment/School Status | Employment/School Status |
| Substance Abuse | Follow-up Care | Follow-up Care | Follow-up Care | Follow-up Care |
| Screening for Previous TBI | Treatment Services | Treatment Services | Treatment Services | Treatment Services |
| Medical History | Hearing/Speech | Hearing/Speech | Hearing/Speech | Hearing/Speech |
| | Substance Abuse | Substance Abuse | Substance Abuse | Substance Abuse |
| | | | Epilepsy | Epilepsy |
| | | | | Litigation |
| | | | | Income/Assets |

Instructions: The Interviews should be administered to the person or persons with the most accurate information. However, sometimes the person with TBI may not recall pre-injury information or may not be an accurate assessor of their current situation. In those situations, it is advisable to ask the significant other the questions on the interview or to ask the significant other to confirm answers provided by the person with TBI.

Any information that is required at a particular follow-up but remains missing should be queried at all subsequent follow-ups until the item is complete. These missing answers should not be defined as "Unknown" on the eCRF if the questions have not yet been asked. Instead, leave these fields blank until the question is asked at a subsequent follow-up.

The examiner should keep in mind that the interview is not a formal, standardized test but rather a conversation you are having with the participant to get the most accurate information to the questions of interest. If the participant has questions or indicates they are not clear what is meant by a question, then the question can be rephrased and explained further so the person understands. Also, be sure the participant understands the time frame involved in the question. Some participants may find some of the questions to be sensitive and personal. Reassure them that their answers are confidential and they are free to not answer any question they do not want to answer. Before administering the questions about pre-injury income and assets, always introduce this section by saying, **"The next questions are about things like your income, wealth, and where you live. We are asking these questions to better understand how income and wealth may help or hinder receiving health care services. We understand that these are sensitive questions, and like the rest of the survey, your answers to these questions will be kept confidential. You are free not to answer any question you find objectionable."**

If the person with TBI is still in the hospital at 2 weeks post injury, then it is not necessary to ask all of the questions on the interview. Use your common sense and do not ask questions that are obviously not applicable for the hospitalized participant (e.g. employment questions). These questions will have an answer code which indicates the question is not applicable.

The interview should be completed solely by the examiner. The examiner will ask the questions and record the responses. However, this can be done with the document on the table allowing the patient to see the form. In the case of ranges and questions with multiple-options, such as those regarding income and net worth, the examiner can easily angle the form so the patient can see the choices.

Control instructions: The paper CRFs for the control interviews have been modified by removing the term "brain" from any questions asking about "brain injury" and by graying out the questions, or responses within questions, that do not pertain to control subjects. For the electronic CRFs in QuesGen, indicate that the patient is a Control Subject. This will trigger the disabling of entire questions (those that are completely grayed out on the paper CRFs) that do not pertain to control subjects. The order of questions and response dropdown menus will be the same. The singular response options that are grayed out on the paper form (as opposed to entire questions, see above) will still appear in the eCRF dropdown on QuesGen, but these responses should not be selected.

Click here: Dropbox\1-TRACK TBI Doc share\Outcomes Core\Assessments\Data Dictionaries or follow the path for the Interview Data Dictionaries containing detailed information and notes pertaining to each question in the Interviews.

## Abbreviated Assessment Battery (AAB)

The AAB should be administered to participants who receive a score < 76 on the Standard GOAT, < 61 on the Written/Modified GOAT or < 19 on the CAP. The test administration sequence is shown below:

AAB Test Administration Sequence

1. Surrogate Interview
2. Confusion Assessment Protocol- Cognitive Impairment Subscale (CAP-COG) and/or 3. Coma Recovery Scale- Revised (CRS-R)
4. Revised-Glasgow Outcome Scale-Extended (R-GOSE)
5. Extended Disability Rating Scale- Post-Acute Interview (E-DRS-PI)

**Measures of Consciousness and Basic Cognition**

*Confusion Assessment Protocol- Cognitive Impairment Subscale (CAP-COG)*

Description: The CAP-COG is a measure of attentional abilities that may be impaired in persons in early recovery from TBI. The cut-point for the score (>18) indicates a level of cognitive impairment that generally indicates that a person has emerged from the Post-traumatic Confusion State (essentially PTA). Scores of 18 and below generally are consistent with acute confusion. Areas assessed include cognitive control (ability to access over-learned information), working memory (ability to hold in memory and manipulate information), vigilance (sustained attention), auditory comprehension, and visual recognition memory.

When Administered: The CAP-COG should be administered in person at 2-weeks, 6 months, and 12 months to participants stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts. Non-verbal participants can be asked to respond by writing or selecting responses non-verbally (e.g. pointing, head-nodding). The CAP-COG cannot be administered by phone.

Order of Administration: After performing below the cut-off score on a GOAT assessment (Standard < 76; Written/Modified < 61), or after meeting all three CRS-R discontinuation criteria.

Form: CAP-COG. ***Note: The stimulus materials (i.e. line drawings required for administration of the Visual Picture Memory Test should be downloaded from Dropbox (****Dropbox\1-TRACK TBI Doc Share\Outcomes Core\Outcomes Administrator Training\Outcomes training materials\CAP and WAIS Test Stimuli****), printed and converted to laminated cards (approximately 3x3).***

Instructions: For the CAP-COG, some initial rapport building is essential. Some tests have two forms. The examiner should always give form A initially and alternate the forms if a participant is assessed with the CAP-COG more than once. The first task of the CAP-COG is the learning trial of the Visual Memory Test. The five stimuli are each presented for 3 seconds and the participant is told, **"I am going to show you pictures of common objects. Look carefully and try to remember each picture."** Name each object as you point to it. Next, the participant is told, **"Now I want you to count forward from 1 to 20 as quickly as you can."** Responses must be completely correct though immediate spontaneous corrections are allowed (e.g. 1, 2, 4, no I mean 3, 4, etc.). No cueing is permitted. Next the participant is told, **"Now I want you to count backwards from 20 to 1."** For this item, the examiner can cue, **"like 20, 19, 18."** Otherwise, responses must be completely correct except for immediate spontaneous corrections. Next the participant is told to **"Say the months of the year"** and to **"Say the months of the year backwards."** No cueing is allowed for these items.

For the Vigilance Test, the participant is told, **"I am going to read you a long list of letters. Whenever you hear the letter H, indicate by raising your hand at the wrist and then putting it back down or saying yes. Let's try these letters to practice, B, H, D."** If, after several attempts, the subject cannot correctly respond to the practice trial, score this item as "0" and continue to the next item. The examiner reads each letter at a rate of one letter each 2 seconds (this is very slow so one must practice to be able to match the correct rate). The examiner puts a slash through each letter the participant responds to and circles any H's that the participant fails to respond to. For the Comprehension Test, the examiner says, **"I am going to ask you some questions that can be answered yes or no. If your answer is yes, nod your head or say yes. If your answer is no, shake your head or say no."** The four questions are then read one at a time to the participant and the examiner notes the participant's responses. *Note that each Comprehension question should be read twice.*

For the Visual Memory Test recognition trial, the examiner says, **"Now I am going to show you some more pictures. Some you have just seen, but others will be shown for the first time. Let me know whether or not you have seen the picture before by nodding your head or saying yes or shaking**

**your head or saying no. Remember indicate yes if you have seen the picture before and no if you have not seen the picture before."** The examiner then shows the 10 pictures (5 from the learning trial, 5 foils) to the participant and the examiner records the participant's responses. If the participant is unsure about a picture, he/she should be encouraged to guess. *Note that the pictures should only be presented and not be named out loud as they were in the first part of the test.* The pictures should be presented in the order they are listed in the CRF starting from the first picture in the left column and going down(i.e for Form A start with: *car, glass, lock, etc.*)

In scoring the items, the participant receives 2 points for counting from 1 to 20 correctly, 4 points for counting from 20 to 1 correctly, 2 points for saying the months in order correctly, and 6 points for saying the months in backward order correctly. There is no partial credit for any of these items. For the Vigilance Test, the number of H's (of 18 possible) responded to correctly is multiplied by 2. The number of other letters (A, B, C, D, E, F, G, I, there are 34 non-targets) responded to is subtracted from this number and this is the final score so the equation is (hits x 2) – (non-target responses) = final score. A final score of 36 is given 4 points, final scores of 30 to 35 are given 2 points, and scores less than 30 are given 0 points. The Comprehension Test score is simply the number of questions answered correctly. A score of 4 correct is worth 4 points, 3 correct is worth 2 points, and 2, 1, or 0 correct are worth 0 points. Finally, for the Visual Memory recognition trial, the score is the number of pictures correctly identified as previously seen or not previously seen. A perfect score of 10 is given 6 points, 9 is given 4 points, 7 or 8 are given 2 points, and scores of 0 to 6 are given 0 points. The CAP-COG final score is the sum of the 7 component scores. These scores range from 0 to 28. Scores > 18 trigger administration of the Comprehensive Assessment Battery.

*Coma Recovery Scale- Revised (CRS-R)*

Description: The Coma Recovery Scale- Revised (CRS-R) is a standardized behavioral assessment instrument designed to measure neurobehavioral function in patients with disorders of consciousness (DOC). The CRS-R is comprised of six subscales addressing auditory, visual, motor, oromotor/verbal, communication and arousal functions. Subscale items are hierarchically-arranged, corresponding to brain stem, subcortical and cortically-mediated functions. Administration and scoring guidelines are manualized and the scale is intended for use by medical and allied health professionals.

When Administered: The CRS-R should be administered to subjects stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts who are found to be nonverbal due to impaired level of consciousness or aphasia on screening examination. For subjects who meet these criteria, the CRS-R should be administered in-person at 2 weeks, 6 months and 12 months post-injury. The CRS-R cannot be administered by phone.

Order of Administration: Following failure on speech intelligibility screening (aphasia or underarousal).

Form: CRS-R

Instructions: The Coma Recovery Scale-Revised is a standardized assessment instrument designed specifically to measure neurobehavioral functions in patients with disorders of consciousness. The examiner must strictly adhere to the administration and scoring procedures described in the *Coma Recovery Scale Revised (CRS-R) Administration and Scoring Manual* which may be found in Dropbox (Dropbox\1-TRACK TBI Doc Share\Outcomes Core\Assessments\Administration and Scoring Guidelines). As described in the CRS-R Manual, the Arousal Facilitation Protocol (AFP) should be performed *prior to administration* of the CRS-R in subjects who appear to be asleep or obtunded. If the participant's level of arousal declines during the examination, the AFP can be repeated as often as necessary so all 6 subscales can be scored. Under these circumstances, a Test Completion Code of 1.0 should be entered (Test completed in full, in person- results valid). Test Completion Code 2.1 and

3.1 (Test attempted but not completed/test not attempted due to cognitive/neurological reason) should not be used when administering the CRS-R as this measure is intended for use with patients who have severe neurologic and cognitive impairment.

If arousal remained poor during the examination despite administration of the AFP (gauged by the length of time the eyes remain open following the AFP), the examiner should specify in the comment box the subscales on which arousal remained poor (excluding the arousal subscale).

CRS-R General Administration and Scoring Guidelines:

- The examiner must be trained in use of the CRS-R and be authorized to administer the scale before initiating data collection. Training is completed by downloading and viewing the CRS-R video link found in the "Example battery administrations for certification" document on Dropbox (Dropbox\1-TRACK TBI Doc Share\Outcomes Core\Outcomes Administrator Training\Outcomes training materials\Example Battery Administrations for Certification), and completing the CRS-R post-test which can be found at: www.surveymonkey.com/s/PKHRQLB. Print, scan, and email the completed post-test to Dr. Sabrina Taylor (sabrina.taylor@ucsf.edu).
- The following items are required for administration of the CRS-R: 1) plastic cup, 2) tennis-size ball, 3) hairbrush, 4) fork, 5) hand-held mirror (approximately 5x8"), 6) unsharpened lead pencil, 7) tongue depressor.
- Prior to administration of the CRS-R, consult the attending physician to determine if there are any local injuries (e.g. fractures, contusions, lacerations, and decubiti), internal lines or systemic complications (e.g. heterotopic ossification) that may require postponement/cancellation of exam.
- Scoring of CRS-R items must be based on direct examination (v. informal daily observations).
- If the subject is in restraints (e.g., wrist, mitten), the examiner should request permission from the attending physician or nurse to temporarily remove the restraint to conduct the examination. If permission is granted and this can be done safely, the items that require freedom of movement (e.g. Motor subscale) should be administered without restraints. After these items are administered, the examiner should ask the nurse to re-apply the restraint before completing the remaining items. If removal of the restraints is not authorized, the examiner should assign the highest score attainable on the affected subscale, note any items that could not be administered and indicate the reason these items could not be administered.
- If the CRS-R discontinuation criteria are met on initial assessment (that is, the participant receives a score of 4 on the Auditory subscale AND a score of 2 on the Communication subscale AND a score of 3 on the Arousal subscale), the examiner should administer the Confusion Assessment Protocol (see CAP Administration and Scoring Procedures).
- If the CRS-R discontinuation criteria are not met on initial assessment, the testing session should be considered complete and the examiner should fill out the CRS-R case report form.
- For subjects who fail to meet the CRS-R discontinuation criteria at the 2-week assessment, the CRS-R should be repeated at the 6 and 12-month follow-ups until these criteria have been met and the participant can be progressed to the CAP (see Outcome Assessment Battery Workflow).
- CRS-R total and subscale scores should be recorded on the CRS-R case report form and entered into the QuesGen CRS-R eCRF.

## Additional AAB Administration and Scoring Guidelines

Administration of the AAB may be complicated by a variety of factors that may influence the administration and scoring of specific measures in the AAB. A number of circumstances have been identified that may confound standard administration and scoring procedures. Examiners should adhere to the additional guidelines below when complications are encountered. There may be other

circumstances that lead to uncertainty with regard to test selection, administration, and scoring that are not included in the list below. The examiner should provide a written explanation (in the "Confounding Variables" field in QuesGen) of any complications that are not addressed by the Test Completion Codes or the additional guidelines described below.

- If Speech Intelligibility is passed, GOAT is failed, and CAP is initiated but failed (score < 18), do NOT administer the CRS-R, Instead, continue with the GOSE/DRS/ Surrogate Interview with the proxy.
- If the CRS-R is attempted but there is NO spontaneous or stimulus-induced eye-opening and the absence of eye-opening is deemed to be due to poor arousal (i.e. wakefulness) rather than a physical issue (e.g., b/l ptosis, lids sewn shut), all CRS-R subscales should be scored as zero and a TCC of 1.0 entered in QuesGen (test completed in full/results valid)
- If discontinuation criteria for the CRS-R are NOT met, the CAP should NOT be initiated and the QuesGen eCRF should be left blank (no TCC's, no From Completion Codes, no confounding variables, etc). *QuesGen is currently working on a way to make the CAP eCRF available only when CRS-R discontinuation criteria are met.*
- If the CRS-R is attempted but there is NO spontaneous or stimulus-induced eye-opening and the absence of eye-opening is deemed to be due to a physical problem (e.g., b/l ptosis, lids sewn shut) and there is indication that the patient has adequate arousal (i.e., purposeful movement), attempt to administer the subscales that do not rely on vision. Make notes in the "Confounding Variables" section of the eCRF and code a TCC of 2.2 (Test attempted not completed due to non-neurological/physical reasons.
- If one of the CAP subscales cannot be administered (e.g., visual memory test due to blindness) do not provide a total score for the CAP. Provide a written explanation in the "Confounding Variables" section and code TCC appropriately depending on the scenario

## Comprehensive Assessment Battery (CAB)

The CAB should be administered to participants who attain a score >75 on the Standard GOAT, >60 on the Written/Modified GOAT or >18 on the CAP. The battery consists of performance based neuropsychological measures, self-report emotional health measures and interviews. Whenever possible, the cognitive measures included in the CAB should be administered first as they are most likely to be negatively influenced by the effects of fatigue, frustration and other non-specific factors.

### Test administration with Spanish speakers

Utilize the Spanish translations of all measures that have been furnished through UCSF when administering the test battery to Spanish-speaking subjects. Use the newly revised GOSE Spanish translation *when administering the GOSE questions in standard form* and, since we do not have a Spanish version of the modified interview which asks questions about the impact of the brain injury specifically, please translate the modified interview questions on the fly.

The CAB test administration sequence is shown below:

CAB Test Administration Sequence

6. Revised-Glasgow Outcome Scale-Extended (R-GOSE) [Interview]

7. Rey Auditory Verbal Learning Test (RAVLT) (5 learning trials, interference list with recall, immediate recall of first list)
8. Trail Making Test A &B (TMT A & B)
9. Wechsler Adult Intelligence Scale (WAIS) IV Processing Speed Index (Coding, and Symbol Search)
10. Rivermead Post-concussion Questionnaire (RPQ) [Self Report]
11. Short Form (SF)-12 Version 2 [Self Report]
12. RAVLT 20 minute delayed recall
13. Quality of Life After Brain Injury – Overall Scale (QOLIBRI-OS) [Self Report]
14. PTSD Checklist (PCL)-5 [Page 1-Interview; Page 2-Self Report]
15. Brief Symptom Inventory (BSI)-18 (If ≥2, proceed to the C-SSRS) [Self Report]
16. Participant/Surrogate Interview [Interview]
17. NIH Toolbox Cognitive Battery
    - Picture vocabulary test
    - Flanker Inhibitory Control and Attention Test
    - List Sorting Working Memory Test
    - Toolbox Dimensional Change Card Sort Test (DCCS)
    - Pattern Comparison Processing Speed Test
    - Toolbox Picture Sequence Memory Test
18. Mayo-Portland Adaptability Inventory (MPAI4-Part) [Interview]
19. Expanded Disability Rating Scale Post-Acute Interview (E-DRS-PI) [Interview]
20. Participant Reported Outcome Measurement Information System (PROMIS) Pain Intensity [Self Report]
21. PROMIS Pain Interference [Self Report]
22. Satisfaction with Life Scale (SWLS) [Self Report]
23. Insomnia Severity Index (ISI) [Self Report]
24. Participant Health Questionnaire (PHQ)-9 (If ≥1, proceed to the C-SSRS) [Self Report]
25. Columbia Suicide Severity Rating Scale (C-SSRS) (Only required if ≥1 on the PHQ-9 or the BSI-18) [Interview]

***Note: The cognitive measures are not administered during the 3-month telephone follow-up. The Brief Telephone Administered Cognition Test (BTACT) is administered by telephone around the date of the 6-month follow-up assessment.***

**Measures of Cognition**

*Rey Auditory Verbal Learning Test (RAVLT)*

Description: This is a test of episodic memory that assesses the ability to acquire 15 words across five learning trials and recall these items immediately after the recall of an interference list and again following a 20-minute interpolated delay.

When Administered: Administer the RAVLT in person to subjects stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at 2 weeks, 6 months and 12 months post-injury.

Order of Administration: The RAVLT is administered after the R-GOSE and before TMT Parts A and B. The 20-minute delayed recall trial is administered after the SF-12 and before the QOLIBRI-OS.

Form: There are three alternate forms of the RAVLT. A different form should be used at each follow-up. Word List 2 should be used at the 2-week follow-up. Word List 3 at the 6-month follow-up and Word List 4 at the 12-month follow-up. Because the RAVLT is also included in the BTACT, it is important to make sure that the List A form, reserved for use with the phone-administered BTACT, is not used during in-person administration of the RAVLT at the 2-week, 6-month or 12-month follow-up.

Instructions: After engaging the participant's attention, the examiner should say, *"I am going to read a list of words. Listen carefully, for when I stop you are to repeat back as many words as you can remember. It doesn't matter in what order you repeat them, just try to remember as many as you can."* The examiner then reads the words aloud with a one second interval between each of the 15 words. Immediately after the words are read, the participant recalls as many as possible, each recorded by the examiner.

Trial II - V

After the participant indicates that no more words can be recalled, the examiner should say, *"Now I am going to read the same words again, and once again when I stop I want you to tell me as many words as you can remember, including words you said the first time. It doesn't matter in what order you say them, just say as many words as you can remember, whether or not you said them before."* Immediately after the words are read, the participant recalls as many as possible, each recorded by the examiner. Be sure to emphasize that words that were recalled on previous trials should be included again on the current trial.

The first time a participant recalls a stimulus word it is counted as correct. If later, in the same trial, the same stimulus word is recalled, the second recall is a perseveration and not counted. If the participant recalls a word that was not on the list, this is considered an intrusion and not counted.

Repeat the preceding instructions for the remaining learning trials.

Interference Trial

After trial V is completed, the examiner should introduce List B by saying, *"Now, I'm going to read another list of words. This time, again, you should say back as many words of this second list as you can remember. Again, the order in which you say the words does not matter. Just try to remember as many as you can."* Record the words remembered from the second list.

Immediate Delay: Immediately after completion of List B, say, *"Now tell me all the words that you can remember from the first list- not the second list, just the first list."* Make sure the participant understands you want just the words from the 1st list and not the 2nd list. Record each of the words recalled.

Recall Trial

After a time span of approximately 20 minutes (during which other testing will have taken place) from the time trial V and the interference trial were completed, the participant should be asked to recall as many of the 15 *original* words as possible. The examiner should say, "A while ago, I read a list of words to you several times, and you had to repeat back the words. Tell me all the words you can recall from that list." Record each of the words the participant can recall.

Problems in Administration: This test can be intimidating for many participants. Acknowledging that it is a difficult task and that they are not expected to get all of the words can help. Encourage them to just do their best.

A participant may neglect words from the former trial thinking they do not have to repeat them each time. Re-explain that they should include words from prior trials.

It is important for the examiner to be able to keep up with each participant as they recall the words. Make sure to practice and record the words as the participant says them on the paper CRF.

At times it is difficult to determine if a participant is actually repeating a word (perseveration) or simply thinking aloud as they run through the list in their mind. It will be the examiner's judgment whether to count these as perseverations or not.

Scoring: For each trial, record verbatim responses on the paper CRF. Correct responses are defined as stimulus words recalled correctly by the participant. Pluralization of a stimulus word is counted as correct (drums for drum).

Count the number of words correctly recalled for each trial (0-15).

Count the number of words correctly recalled for the 20 minute delay. This raw score will also be entered into QuesGen. Perseverations and intrusions are not scored or recorded on the CRF.

*Trail Making Test (TMT)*

Description: The TMT is a measure of attention, speed, and mental flexibility. It also tests spatial organization, visual pursuits, recall, and recognition. Part A requires the individual to draw lines to connect 25 encircled numbers distributed on a page. Part A tests visual scanning, numeric sequencing, and visuomotor speed. Part B is similar except the person must alternate between numbers and letters and is believed to be more difficult and takes longer to complete. Part B tests cognitive demands including visual motor and visual spatial abilities and mental flexibility. Both sections are timed and the score represents the amount of time required to complete the task.

When Administered: Administer TMT A and B in person to subjects stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at 2 weeks, 6 months and 12 months post-injury.

Order of Administration: Administer TMT after the RAVLT and before the WAIS IV Processing Speed Index.

Form: TMT A and B

Instructions: The Trail Making Test consists of two parts, A and B. The participant will need a pencil to perform each part. The examiner uses a red pencil to mark the participant's errors as the tests are in progress. Each part has its' own sample which the examiner administers to help explain the instructions and determine the participant's comprehension of the task. The examiner starts timing both part A and B as soon as the instructions are completed and the participant is signaled to begin. Do not stop timing until the participant completes each respective part or the discontinuation time points have been reached.

**Administration of Part A:**

The sample of this part consists of 8 circled numbers distributed out of order in a small rectangular box on the front side of the Part A form. Patients are required to connect the circled numbers in order by drawing a line with their pencil from one to the other as quickly as they can. The examiner gives the instructions and the participant attempts the sample. If there are no errors made on the sample or if it

is otherwise clear that the participant understands the instructions, the examiner records the time in seconds, notes any errors in parentheses next to the time, and then proceeds with the instructions for Part A.

Part A on the back of the form is comprised of more numbers. This time the participant must connect circled numbers in the proper order from 1 to 25. When a participant makes a mistake by drawing a line to a number out of sequence the examiner draws a red slash mark next to the incorrect circle, across the participant's own line.

Simultaneously, the examiner should bring the error to the participant's attention by saying, *"No, where do you want to go from here?"* pointing to the preceding number. The examiner should be careful not to correct the participant until the participant actually reaches the incorrect circle since many patients will correct themselves before actually reaching the wrong location. If the participant either states the right number or then draws the correct line, the examiner allows the test to proceed. If the participant gives an incorrect verbal response when the examiner asks, *"Where do you want to go from here?"* this is considered a verbal error. The examiner keeps tally of the number of verbal errors committed by making a small red mark at the top of the page (the closest part of the page to the examiner). The mark should be made lightly and without distracting the participant from the task. The examiner then says, "No", and the participant must figure out where to go next before continuing. On the other hand, if the participant does not give a verbal response to the examiner, but then goes on to draw a line to another incorrect circle, then the same procedure is followed that was employed when the participant committed the first written error; draw a red slash mark across the participant's line and bring the participant back to the preceding number in the same fashion as before. The examiner does not stop timing when errors occur. Part A can be discontinued at 100 seconds.

Trails A Sample

Say to the participant, **"On this page are some numbers (place the Trails A form sample side up in front of the participant and point to the numbers in the sample box). Begin at number 1 (point to 1 with the tip of your red pencil)* and draw a line from 1 to 2 (pointing), 2 to 3 (pointing), 3 to 4 and so on, in order, until you reach the end (point to the circle marked 'end'). Begin here (point to number 1) and draw your line as fast as you can. Ready! Go!"**

Trails A Test

After the sample is completed and the examiner is sure that the participant understands the task, turn the paper over to Part A. Say, **"On this page there are numbers from 1 to 25. Do this the same way. Begin at 1 (point to number 1) and draw a line from 1 to 2 (pointing), 2 to 3 (pointing), 3 to 4 and so on in order, until you reach the end (point to the circle marked 'end'). Remember to work as fast as you can. Ready! Go!"** Part A can be discontinued at 100 seconds.

**Administration of Part B:**

Part B and its sample are on a separate form. They consist of a series of numbers and letters to be connected in order, alternating back and forth between the series of numbers and the series of letters. Again patients are to draw their line as quickly as they can.

When an error is made the examiner says, *"No",* draws a red slash over the participant's line, brings the patients' attention back to the preceding circle by pointing, and asks them where they would go from there, in the same fashion as instructed in Part A.

Since Part B is considerably more complicated than Part A, cognitively speaking (the participant must now alternate in the proper order between 2 quite different sequences) many patients will need an additional interaction with the examiner in order to successfully complete the test. Essentially, errors made in Part A are errors in sequencing (i.e. the participant chooses the wrong number that comes next the sequence). On Part B a participant can make an error in sequencing by choosing either the wrong number or letter, or an error in category (i.e. the participant chooses a number when they should have chosen a letter or a letter when they should have chosen a number).

Both types of errors are handled in the same way initially. The examiner says "No" when the participant draws a line to the wrong circle and asks them where they should go from there. However, if the participant makes another mistake immediately afterward either verbal or written and the error is one in category, then an additional line of questioning is followed. After noting the error in the proper fashion the examiner asks, *"What do you want next, a number or a letter?"* If the participant responds correctly, then the examiner asks, *"Which number (or letter)?"* If the participant responds to this question correctly as well, then the test proceeds. If on the other hand the participant responds incorrectly the examiner says "No", marking the error, and then asks the question again. After the participant successfully answers the first question the examiner continues by asking, *"Which number or letter?"* The participant must figure out which circle to go to next before they go on.

The examiner should be particularly careful to note errors each time they occur. Often examiners can become so involved with their interactions with a participant that they forget to note some errors. The examiner does not stop timing when an error occurs. Therefore, errors should be dealt with quickly so as to avoid adding extra time to the participant's performance.

Due to the seemingly insurmountable difficulty some patients encounter when attempting Trails B, the examiner can chose to discontinue the test after 300 seconds. If the participant is close to the end of the test when this time is reached or if the participant is making discernible progress, the examiner should probably allow the participant to finish. With patients who are having extreme difficulties and are making little, if any, progress it is permissible to discontinue before the 300 second limit. The examiner should use conservative judgment in choosing to discontinue before the allowed time has expired.

Trails B Sample

Say to the participant, **"On this page are some numbers and letters. (Place Trails B in front of the participant and point to the sample box) Begin at 1 (point) and draw a line from 1 to A (raise pencil up and move it slowly to A, then hesitate allowing the participant to realize what you have done), from A to 2 (point), from 2 to B (point), from B to 3 (point) from 3 to C and so on in order until you reach the end (point). Remember, first you have a number then a letter, then a number then a letter and so on. Draw your lines as fast as you can. (If the participant still seems a little confused add again Remember number-letter, number-letter). Begin here (Point to 1). Ready. Go!"**

If the participant has difficulty completing the sample correctly, re-explain the instructions and demonstrate again. After the second demonstration say, **"You see, what I want you to do is to go back and forth between numbers and letters in order. You do not want to go to 2 numbers in a row or 2 letters. Go from a number to a letter and then back to a number again and so on in order, until you reach the end."** Occasionally, it is necessary to get out another test form to have the participant try the sample once again.

Trails B Test

After the examiner is reasonably sure that all possible efforts have been made to help the participant understand proceed to Part B. Say, **"On the page are both numbers and letters. Connect them in the same way. Begin here (point to 1) And draw a line from 1 to A (pointing to each number and letter as you deliver instructions), A to 2, 2 to B, B to 3, 3 to C and so on in order until you reach the end (point to the circle marked end). Remember, first you have a number then a letter, then a number and then a letter, and so on. Do not skip around but go from one circle to the next in the proper order. Draw your lines as fast as you can. Begin here (point). Ready, go!"** Part B can be discontinued at 300 seconds.

Problems in Administration

Relatively few problems are encountered when administering Part A. However, part B can present considerable difficulty for some patients. Follow the rules outlined on the previous pages for dealing with participant errors. Repeat instructions whenever necessary.

Occasionally the examiner may not be quick enough to catch an error before the participant continues on to another circle. Mark the error and draw the participant's attention back to the circle preceding the mistake following the protocol outlined per the instructions.

It is not necessary that the participant actually touch the circle, if it is clear to the examiner the participant intended to touch it. However, remind the participant to touch each circle so that the examiner does not have to deal with borderline situations. Also, some patients may draw their line through a circle on their way to the correct circle. This is not an error so long that it is clear they did not intend the incorrect circle as their target.

Some patients may accidently cover a number or letter with their hand that they are trying to find. The examiner is not allowed to tell them that their hand is covering a circle. If the participant spends an inordinate amount of time looking for a covered circle it is worth noting this in the observations.

Some patients may experience a visual neglect. For example it is not uncommon for a participant with a right hemisphere stroke to experience a left neglect in which they miss the left side of the page. It is permissible for the examiner to give simple cues such as 'make sure you look to the left' or 'make sure you are scanning the entire page'. The examiner may not point out specific numbers/letters.

Some patients may become bored with the examiner's somewhat repetitive instructions. The examiner should not cut corners when giving the instructions. Each participant should be administered the instructions in the standard fashion. Even though a participant may understand, there are visual cues given (the location of the first few circles are pointed out). A participant who does not receive the step by step instructions or does not choose to attend to them may spend unnecessary time looking for circles the examiner already pointed out. Typically if the examiner says something like, "I can see you already know what to do but I need to give the complete instructions" this will be enough to allow the examiner to continue and the participant to attend.

Examiners should not allow the participant to start questioning them. For example, 'Is the next letter G?' Tell the participant to draw a line to the circle that they think comes next.

Scoring: The time to completion in seconds should be recorded separately for Parts A and B. The maximum score for Part A is 100" with 101" indicating the test was discontinued. The maximum score for Part B is 300 seconds with 301" indicating the test was discontinued.

*Wechsler Adult Intelligence Scale IV- Processing Speed Index (WAIS IV-PSI)*

Description: The Processing Speed Index consists of two subtests: the Symbol Search test and the Coding test.

When Administered: Administer WAIS IV PSI in person to subjects stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at 2 weeks, 6 months and 12 months post-injury.

Order of Administration: Administer the WAIS IV PSI after TMT A and B and before the RPQ.

Form: WAIS IV PSI

*Instructions for Symbol Search:*

Symbol Search is the first subtest, coupled with Coding, which makes up the Processing Speed Index score of the WAIS-IV.

Instructions are found on page 130 of the administration manual.

Place the Symbol Search test form in front of the participant with a pencil and say, **"Look at these shapes (point across the first demonstration item). One of these shapes is the same as one of these shapes here. This shape is the same as this shape here (point to the matching symbols), so I draw a line through it, like this** (draw a diagonal line through matching symbol in search group).

Point across the second demonstration item and say, **"Look at these shapes. This shape is the same as this shape here (point to the matching symbols), so I draw a line through it, like this"** (draw a diagonal line through matching symbol in the search group).

Point across the third demonstration item and say, **"Now look at these shapes. In this case, neither one of these shapes here is the same as any of the shapes here, so I draw a line through the NO box, like this"** (draw a diagonal line through NO box).

**"If you see a shape over here (point across search group for the second demonstration item) that is the same as one of these shapes, draw a line through the shape. If you do not see a shape over here (point across search group for the third demonstration item) that is the same as one of these shapes (point to the 3rd demonstration item), draw a line through the NO box.**"

Sample Items

Hand the participant a pencil preferably without an eraser and say, **"Now you do these here. Go ahead."**

Make sure all 3 samples are completed correctly. Point out any errors and re-explain if necessary.

Test Items

When it is clear that the participant understands, open the test booklet and say, **"When I say go, do these the same way. Start here (point), go in order, and don't skip any. Work as fast as you can without making mistakes until I tell you to stop. When you finish the first page, go to the second page and the following pages. Are you ready?"**

Begin timing. At 120 seconds say **"Stop"**.

Problems in Administration:

Occasionally a participant will ask if the shapes need to be oriented the same way. Tell them 'yes' they need to be exactly the same. Sample 2 is a good example of this.

Be prepared to help turn the page quickly so as not to waste time.

If the participant has a visual field cut or a neglect the examiner may need to remind them to scan the entire page. Tell them to "look left" if necessary.

Occasionally a participant will ask if both target shapes need to be there or if both can be in a particular group. Clarify that it will be either one or the other, or neither – never both.

Make sure they understand they are to go as quickly as possible (but without making mistakes).

Scoring the Symbol Search test: Using the scoring template, mark any incorrect responses. For each page, count the number of correct responses and the number of errors. Record each at the bottom of the page. A skipped trial is not counted as an error. Total the number of correct responses. Total the number of errors.

*Instructions for Coding:*

Coding is the second subtest, coupled with Symbol Search, which makes up the Processing Speed Index score of the WAIS-IV.

Instructions are found on page 152 of the administration manual.

Demonstration Items:

Place the Coding response page in front of the participant along with a pencil preferably without an eraser. Say, **"Look at these boxes. Each box has a number in the top part (point to key 1-9) and a special mark in the bottom part (point out the symbols). Each number has its own mark."**

Next, pointing to the demonstration items, say, **"Down here, the boxes have numbers in the top parts but are empty in the bottom parts. You are to draw the marks that belong in the empty boxes, like this."**

**"Here is a 6. The 6 has this mark (point), so I draw that mark in the box, like this."**

**"Here is an 8. The 8 has this mark, so I draw that mark in the box."**

**"Here is a 3. The 3 has this mark so I draw that mark in the box."**

Sample Items:

**"Now you do these. Stop when you get to this line."** Point to the sample items. Make sure all samples are completed correctly. Point out any errors and ask the participant to make corrections and re explain if necessary.

When it is clear the participant understands the task, move on to the test. Say, **"When I say go, do these the same way. Start here, go in order, and don't skip any. Work as fast as you can without making mistakes until I tell you to stop. Are you ready?"**

Begin timing. At 120 seconds say, **"Stop."**

Problems in Administration: Make sure the participant understands the importance of speed. If it appears that the participant is too concerned with neatness, tell them it's more important to complete as many as they can in the time allowed.

Don't allow the participant to waste time by tracing over lines already drawn etc.

Don't allow erasure – it wastes time. Encourage the participant to write over an incorrect response. Some examiners remove the erasers from the pencils to eliminate this possibility.

Make sure they don't skip around.

If the participant has a visual field cut or neglect the examiner may need to remind them to scan the entire page. Tell them to 'look left' if necessary.

Scoring the Coding Subtest: Using the scoring template, mark any incorrect responses. Count the number of correct responses. This is the raw score.

*NIH Toolbox*

Description: The NIH Toolbox is a set of brief, comprehensive assessment tools administered via a laptop (examiner) and monitor (participant). This study protocol will use the Cognitive battery (minus the Reading subtest) of the Toolbox consisting of 7 subtests designed to measure executive function (Flanker and Dimensional Change Card Sort), episodic memory (Picture Sequence Memory Test), working memory (List Sorting Working Memory Test), processing speed (Pattern Comparison Processing Speed and Flanker), language (Picture Vocabulary Test) and attention (Flanker and Dimensional Change Card Sort Test). Each site will need a laptop, monitor, speakers, keyboard and mouse for the administration of the cognitive battery.

When Administered: Administer the NIH Toolbox in person to participants stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at 2 weeks, 6 months and 12 months post-injury.

Order of Administration: Administer the NIH Toolbox after the Participant/Surrogate Interview and before the MPAI.

Form: None. The Toolbox is administered on-line.

Staff Responsible: Data Collector

Instructions: In most cases the instructions are displayed on the computer for the examiner to read or presented by a prerecorded voice. Most of the subtests will have a practice prior to beginning each test. In addition to the participant needing to understand the instructions, they also need to learn how to respond, move objects on a screen, and use the mouse and arrow keys on a keyboard.

The Toolbox website provides a wealth of information including, an explanation and video demonstration of each subtest, and training and administration manuals.

The NIH Toolbox website can be accessed at http://www.nihtoolbox.org.

Under the 'Quick links' section, clicking on the e-learning tab will direct the examiner to an overview of the Toolbox battery. Focus on the Cognitive battery and computer set up. The menu on the left side of the screen will access the manuals. Each may be downloaded or sections printed as necessary.

NIH Toolbox Supplies and Equipment requirements tab gives a detailed description for the computer/monitor and other equipment.

From the home page: Scrolling down the page on the right there is the link that will go to the demonstration videos for each subtest. These are large files so may take awhile to open.

Programming for several subtests will automatically adjust to the level of the participants' abilities. For example, if a participant does exceptionally well on the 15 item memory task, the next series will progress to an 18 item sequence. In the Vocabulary subtest the items may adjust to easier or more difficult items based on the participant's performance. Automatic discontinuations are also set in place according to performance.

**Setup of the computer and monitor:**

-External Display on left, laptop on right.
-No matter which Internet Explorer version you're using, if you don't have a menu bar visible, right click somewhere near the top edge of the window and select "Menu Bar".
-On the Menu bar click "Tools" --> "Compatibility View Settings". A window will open up. Add "www.assessmentcenter.net" as a website. Close.
-On the Menu bar click "Tools" --> "Internet Options". Pick the "Privacy" tab. On this page you can have the "Pop-up Blocker" box checked, but make sure to click "Settings" and add "www.assessmentcenter.net" to the list of allowed sites.
-Display settings for External Display should be 1440 x 900
-Go to "Display" settings under Control Panel, select External Display under "change the appearance of your displays") and check the "make this my main display" box. Click the laptop display icon/screen and make sure that under the "Multiple displays" drop down the "Extend these displays" is selected. (You can also access the "Displays" section of the Control Panel simply by right-clicking on your desktop and selecting "Screen resolution" from the menu ribbon).
-Double check that the "External Display" (whatever your external monitor is, if you got it from Mary it's the ACER one) is dragged to the left of the laptop ("Mobile PC Display"). If not, then drag/arrange as appropriate.
-Tests included: Picture Vocabulary; Flanker Inhibitory Control & Attention; List Sorting Working Memory; Dimensional Change Card Sort; Pattern Comparison Processing Speed; Picture Sequence Memory; Oral Reading Recognition.

**Administration of the Toolbox:**

-Sign in to assessmentcenter.net.
-Go to the "Administration" tab on the top.
-Click "Find/create Login". You will be directed to another screen.
-Check "create participant login" and type in a Study ID (e.g. 01-1001) according to your Site Code-Study ID. (Site Codes: BCM-TIRR = 01, MGH-Spaulding = 02, U Miami = 06, UW = 10)
-Create a Password. It should be the same as the participant login.-Check "Yes" for consent. The other fields (i.e. study code, baseline, etc) should be left blank.
- Click "Participant Details" on the top bar and input Age, Gender, Ethnicity, and Race. *Do **not** enter the date of birth. Proper completion of these fields is necessary for proper scoring of the Toolbox.* Click "Register".

-There should now be a link on the bottom that says "The registered participant can assess their study at:"
-Open a new window via your browser and paste the link in. You should be ready to start.
-The participant screen will be on the external display. The administrator screen will be on the laptop display.
-If you encounter problems with test administration (i.e. a test is taking longer than expected to load due to connectivity issues, a test is skipped due to administrator error or patient request, etc), please note these observations on the NIH Toolbox paper CRF and in QuesGen.

**Tips:**
-It is best to share 1 mouse instead of having 2. This way you can pass the mouse to the patient when they need to use it, and take it back when they no longer need it, or when you need to click.

The Test Completion Codes should be used when a Toolbox measure cannot be completed.

*Brief Test of Adult Cognition by Telephone (BTACT)*

Description: The BTACT is a battery of measures designed to assess cognitive status over the telephone. The battery consists of a Word List Learning trial (1 trial of the RAVLT) with a delay, Digit Span Backward, Category Fluency, The Red/Green Test, a Number Series Test (reasoning), and Backward Counting.

When Administered: Administer the BTACT by telephone to participants stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts within ±7 days of the originally scheduled 6 month follow-up. The examiner should call the participant approximately 2 weeks before the 6-month follow-up date to remind the participant about the upcoming 6-month follow-up assessment and to schedule the date for administration of the BTACT. BTACT testing should be conducted no more than 7 days before or after the date of the 6-month follow-up. The BTACT should not be administered on the same day as the in-person CAB to avoid interference effects between the standard RAVLT and the BTACT Word List Learning trial. For further information regarding administration and scoring guidelines, please see the BTACT manual at Dropbox \1-TRACK TBI  Doc Share\Outcomes Core\Outcomes Administrator Training\Outcomes training materials\Example Battery Administrations for Certification.

Order of Administration: 1) word list recall, 2) digits backward, 3) category fluency, 4) red-green test, 5) number series and 6) backward counting.

Form: BTACT

Instructions: It is important for the examiner to ensure a smooth delivery and to accurately time and record responses over the phone. The battery should be introduced as follows, “Next, I will ask you to try and do some exercises that involve remembering and making judgments about words and numbers. These tasks are not harmful in any way. If you prefer not to answer any question, just let me know and we will go on to the next question.

Now you will hear some words and numbers. Please do not use a paper and pencil for any of the questions. We suggest that you close your eyes while you are doing these to help you concentrate. Some of the questions will be easy for you, and some will be harder. We do not expect anyone to get all of these correct – just do the best you can.”

**1. Word List Recall:**

**"I am going to read a list of 15 words. Listen carefully. When I am finished, you are to repeat as many of the words as you can remember. It doesn't matter in what order you repeat them. Just try to remember as many as you can. I will say each word only one time, and I cannot repeat any words. You will have up to one and a half minutes, and I will not say anything until I tell you that your time is up. Do you have any questions? Are you ready?"** The examiner reads the list with a 1 second spacing between each word.

**"Now tell me as many words as you can remember."**

Begin timing and record each correct response. *Record each word recalled in order* by writing down the first 1-2 letters of each word in the space above or ticking off each word, as well as repetitions of same word and intrusions. If person stops before 1 1/2 minutes is up, say, **"There's still time left, can you think of any more?....Good, now let's go on."**

Scoring: Plurals of a word are scored as correct. Words not on the list or variants of words on the list (e.g. farm, home) are Intrusions.

The raw score is the total number of words recalled.

**2. DIGIT SPAN BACKWARD** (2.5 minutes)

*WAIS III (1997)*

Say, **"I am going to say some strings of numbers, and when I am done I would like you to repeat them backwards, in the reverse order from which I said them. So if I said "3, 8", you would say "8, 3". Do you understand? The sets will get larger as we go."**

Read in monotone, 1 number per second. Avoid reading the numbers in groups. Drop your voice on the last digit to indicate it is time to respond. If they get the first trial on one level, move on to the next level. Discontinue after 2 trials missed on a level.

Scoring: The interviewer checks off correct trials and notes incorrect trials with a 0. When the participant gets one trial correct at a level, move on to the next level. If the first trial is incorrect, give a second trial. Discontinue when no correct response is given at a level. Enter the highest level reached (this is the longest number of digits correctly repeated in sequence) (Range 0, 2-8): _____

If the participant immediately self-corrects, do not count it as an error ("9, 6,..no, 9, 2, 6").

The examiner should record whether each trial of each number series was passed (i.e. correct) or failed (incorrect) on the CRF.

**3. CATEGORY FLUENCY** (1.5 minutes)

*Drachman & Leavitt (1972)*

Say, **"Now I am going to name a category and you will name things that belong in that category. Let's practice with the category "fruit". You could say peach, or pear. Can you think of any other fruits? (Wait for 2 correct items). In a moment I will give you another category. When I say begin, you will name all the things from this new category you can think of as fast as you can. You will have one minute to do this. I will let you know when your time is up. The new category is animals. Do you have any questions? Ready? Begin."**

Begin timing. At 60 seconds say, **"Stop".**

If the participant stops before 1 minute is up, say, **"There's still more time, can you think of any more?"**

The examiner records each of the participant responses. It may be necessary to write only the first couple letters of a particular response in order to keep up with the participant. These responses can be filled in later if necessary.

If person asks whether birds, fish, insects, reptiles, etc. are acceptable, say yes. If a participant says a category such as "bird", then names a specific, "robin", give credit for each. Do not accept mythical animals such as dragons and unicorns.

Accept birds, fish, insects, etc. as animal names. Do not inform participants of this ahead of time, but if they specifically ask you if these are acceptable while naming items, say, **"yes, go ahead"**.

If a participant says a category such as "bird", then names a specific, "robin", credit is given for each of these responses. Another example is "bear" and then "polar bear", "panda", etc.

Accept baby animal names, even when the adult version has already been said. For example, if a participant says "dog" and then "puppy", we accept both as unique responses. Accept humans, dinosaurs and other extinct creatures (i.e. saber-tooth tiger) as animals. Do not accept processed animals (i.e. beef or pork) as animal names.

Scoring: Record totals for number of correct responses, number of repetitions and number of intrusions (incorrect responses).

**4. Red/Green Test**

"**Next I am going to see how quickly you can respond to the words RED and GREEN. Every time I say RED you will say STOP, and every time I say GREEN you will say GO. Try to be accurate, but respond as quickly as you can. So when I say RED you will say…(STOP)**

**And when I say GREEN you will say…(GO)**

**Do you have any questions? Let's begin. This will last about 1 minute."**

Do 20 trials. Allow 1 second between response and next cue. Record accuracy with 1 for correct answers, 0 for incorrect or self-corrections, X for invalid trials [trials are scored as invalid if the participant produces extraneous noises such as coughs, comments, or there are other external distractions that would invalidate the latency].

Score the first clear response. Self corrections are incorrect.

**"Now you will do just the reverse of what you have been doing. So when you hear RED you will say GO, and when you hear GREEN you will say STOP. Do you have any questions? When I say RED you will say…(GO) and when I say GREEN you will say…(STOP)**

**Try to be accurate, but answer as quickly as you can. This will take about 1 minute."**

Do 20 trials. Allow one second between response and next cue. Record accuracy with 1 for correct answers, 0 for incorrect or self-corrections, X for invalid trials.

**"Now we are going to mix up these two types of responses. When I give the cue NORMAL, you will respond the way you did at first: red means stop, green means go. But when I say REVERSE,**

**you will give the reverse responses: RED means GO, GREEN means STOP. We will alternate between the NORMAL and the REVERSE every few trials. Let's try a few for practice."**

Administer the practice trials. Ask the participant if they have any questions.

**"Try to be accurate, but answer as quickly as you can. This will take about 1 minute."**

Administer Red/Green switching task.

Problems in Administration:

This subtest will take some practice. There are a lot of back and forth quick exchanges between the participant and examiner. Responses need to be recorded quickly and accurately.

Scoring decisions need to be made quickly as well. The first complete word is the scoreable response. If a participant were to respond with a response such as s.s.s.go. 'Go' would be the scoreable response. Self-corrections are not counted as correct.

Scoring: Record the totals for number of correct responses and number of false positive errors.

**5. NUMBER SERIES (REASONING TEST)** (2.5 minutes)

*Salthouse & Prill (1987)*

**"In the next exercise I will read you a series of numbers that may get larger or smaller in value. At the end you will try to figure out what the next number would be. So if the numbers were 2, 4, 6, 8, 10, then the next number would be 12. After I say each number I will pause for as long as you need, and then you should say "okay" when you are ready for me to go on to the next number in the group. So if I said 2, you should say "okay" when you are ready for me to go on to the next number, then I say 4, you say "okay", 6, "okay", 8, "okay", 10, and at the end I will ask you what you think the next number would be. In this case the next number would be 12, as each number has increased by 2.**

**Let's try one for practice: 35 (okay), 30 (okay), 25 (okay), 20 (okay), 15 (okay) AND the next number would be….???? (The answer should be 10 as each number has decreased by 5). There will be different patterns, and some of these will be harder than others, so just do the best you can. If you are not sure of the answer, it is okay to guess. Do you have any questions?"**

Pause after each of the first 4 items for okay response; after the last item, say AND the next number is….? There is no discontinuation rule for this subtest.

Record the response given for each problem. If the participant immediately self-corrects and gets the right answer, give credit (e.g. "47... no, 48). Give a small breather after each trial. You can say "Okay. Are you ready for another? The next set is..." after each trial.

**6. BACKWARD COUNTING** (45 seconds)

**"Next, I would like to see how fast you can count backwards. When I give the signal to begin, start counting backwards from 100 out loud, as fast as you can. So you will say 100, 99, 98 and so on. You will have half a minute. Do you have any questions? I will let you know when the time is up."**

Begin timing. At 30 seconds say, **"Stop"**.

On record form:

/ Over skipped numbers (omissions)

O Over top of numbers to denote number reversals

# For incorrect responses (errors)

Record the last number reached, and also keeps track of the number of errors. If a number is omitted entirely, it is an error (99, 98, 96....). Each number omitted counts as one error. So (99, 98, 95, 94...) would be 2 numbers missed, 2 errors.

Occasionally a participant will skip an entire decade of numbers: e.g. go from 91 to 80. This counts as 10 errors. Repeating the same number ("99, 98, 97, 97, 96") is also scored as an error; If someone makes an error but *immediately* corrects himself, e.g. "eighty-nine, eighty-eight, eighty-si – no – eighty-seven, eighty-six" we would *not* count that as an error. The key here is that the participant realizes the mistake immediately while making it, "repairs" and keeps going. This will be rare. However, if someone makes an error and then goes back and corrects it after having already done it (e.g. "eighty-nine, eighty-eight, eighty-six... – no – eighty- seven, eighty-six, eighty-five...") this would count as one error. The key here is that the error was made and *then* afterward the participant realized it and corrected it. Note that this "eighty-six" though technically a repeat of the previous eighty-six, is not counted as a second error, because it was used in the process of correcting the first error.

Saying the wrong number – but not a skip or repeat is rare but not unique. Consider the case where a participant says the wrong number, but does not actually skip or repeat anything, e.g. "...92, 91, **80**, 89, 88, 87, 86, 85, 84, 83, 82, 81, **70**, 79, 78, 77..." Here the participant has said 80 where he should have said 90, and said 70 where he should have said 80, but counted all of the other numbers correctly in the right sequence. In this case you would count just one error for 80 and one error for 70 (you wouldn't consider this to be skipping decades of numbers).

Scoring:

Record the last number reached.
Record the number of errors (reversals, skips, and incorrect numbers)
Record the total number of digits produced (100- (number reached + number of errors))
Record the time if less than 30"
After this subtest say, Good, one more question.

SHORT-DELAY WORD RECALL (40 seconds on average)

Say, **"Do you remember the very first list of 15 words that I read to you in the beginning? It was the very first thing we did."** (WAIT FOR PARTICIPANT TO RESPOND YES. MAKE SURE THEY UNDERSTAND THAT IT IS THE WORD LIST, NOT THE CATEGORY FLUENCY TEST). **"I want you to tell me as many of the words from that list as you can. You will have up to one minute. I will tell you when your time is up."** *(Record words recalled, including intrusions and repetitions*.) *If person stops before 1 minute is up, say,* **"there is still more time; can you think of any more?"**

## Self-Report Measures

The TRACK-TBI self-report measures include a variety of questionnaires designed to capture specific symptoms tied to TBI, ratings of psychological health, levels of social participation and quality of life. These measures can be administered in-person or by telephone.

The examiner reads the instructions and presents the form to the patient. If the examiner has any doubt about the patient's reading level or ability to understand the content, the examiner should ask the participant to read and complete the first couple of items and make a determination. If it is clear the participant can read and understand the instructions, then allow the participant to complete the questionnaire on his/her own. The examiner should have a good idea about the cognitive capabilities of the subject based on the neuropsychological measures and the R-GOSE, which precede these measures.

If the participant does need examiner assistance, then the examiner should read the items out loud and allow the participant to mark the form as independently as possible. The examiner may also record the responses for the subject if necessary.

In all cases, the examiner should quickly scan the questionnaire before moving on to another measure to make sure that all of the questions are answered. The examiner should also be available to answer any of the participant's questions. For example, if they are unsure of the meaning of a word or if they need clarification of the time frame, etc. The examiner should never lead the participant as far as the content of the question is concerned.

The following are considered self-report measures: RPQ, SF-12, QOLIBRI-OS, PCL-5 (page 2), BSI-18, PROMIS Pain Intensity, PROMIS Pain Interference, SWLS, ISI, and the PHQ-9.

The following are considered Interview-type self-report measures and should be conducted interview-style: MPAI, PCL-5 (page 1), and the C-SSRS.

### Measures of TBI/Post-Concussive Symptoms

*Rivermead Post-Concussive Symptom Questionnaire (RPQ)*

*Original: King NS, Crawford S, Wenden FJ, Moss NE, Wade DT (September 1995). "The Rivermead Post Concussion Symptoms Questionnaire: A measure of symptoms commonly experienced after head injury and its reliability." J. Neurol. 242(9): 587–92. doi: 10.1007/BF00868811. PMID 8551320.*

*Scoring: Eyres S, Carey A, Gilworth G, et al: Construct validity and reliability of the Rivermead Post-Concussion Symptoms Questionnaire. Clin Rehabil 2005; 19:878–887.*

Description: The Rivermead PCS Questionnaire (RPQ) was originally developed as a measure of severity of symptoms following MTBI. It consists of 16 post-concussion symptoms including headaches, dizziness, nausea/vomiting, noise sensitivity, sleep disturbance, fatigue, irritability, feeling depressed/tearful, feeling frustrated/ impatient, forgetfulness, poor concentration, taking longer to think, blurred vision, light sensitivity, double vision and restlessness. In the original version of the RPQ, participants are asked to rate the degree (on a scale of 0 to 4) to which a particular symptom has been absent or a mild, moderate or severe problem over the previous 24 hours compared with premorbid

levels. Note that the five-point rating scale asks the respondent to compare his/her current symptoms (if any) to symptoms experienced prior to the current injury. Thus, a score of 0 (i.e., "not experienced) means the symptom was not previously experienced and is currently not a problem. A score of 1 (i.e., "no more of a problem") indicates that a symptom that was present before the injury has not worsened since the current injury. Scores of 2, 3 and 4 (i.e., "mild," "moderate," and "severe" problem) imply that there has been a mild, moderate or severe *worsening* of a symptom that was present before the current injury. For purposes of the TRACK TBI study, a 7-day observation period will be used instead of the 24 hour window.

When Administered: The RPQ should be administered to participants stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at the 2-week, 6-month and 12-month in-person follow-ups, and during the 3-month telephone follow-up. The RPQ should be administered to patients only (not significant others).

Order of Administration: Administer the RPQ after the WAIS IV PSI and before the SF-12.

Form: RPQ

Instructions: Provide an RPQ case report form for the participant. Read the following instructions **"After a head injury or accident some people experience symptoms that can cause worry or nuisance. We would like to know if you now suffer any of the symptoms on the form in front of you. Because many of these symptoms occur normally, we would like you to compare yourself now with before the accident. For each symptom in the list, please circle the number that most closely represents your answer. The answer options are:**

**0 = not experienced at all**
**1 = no more of a problem**
**2 = a mild problem**
**3 = a moderate problem**
**4 = a severe problem**
**Compared with before the accident, do you now (i.e. over the last 7 days) suffer from:...?"**

*Participant Reported Outcome Measurement Information System Pain Intensity Instrument (PROMIS-Pain Intensity)*

Description: The PROMIS Pain Intensity instrument assesses how much a person hurts. Respondents are usually able to provide quantitative pain intensity estimates relatively quickly, and most measures of pain intensity tend to be closely related to one another. This suggests that pain intensity is a fairly homogeneous dimension, and one that is relatively easy for adults to identify and gauge. The 3-item Pain Intensity short form will be used in this study. The short form is generic rather than disease-specific. The first two items on the short form assess pain intensity over the past seven days while the last item asks participants to rate their pain intensity "right now".

When Administered: PROMIS Pain Intensity should be administered to subjects stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at the 2-week, 6-month and 12-month in-person follow-ups, and during the 3-month telephone follow-up.

Order of Administration: The PROMIS Pain Intensity scale should be administered directly after the E-DRS-PI and before PROMIS Pain Interference.

Form: PROMIS Pain Intensity Short Form 3a

Instructions: Provide the participant with the PROMIS Pain Intensity response sheet, review the 5-point Likert-style rating scale (e.g. 1 = had no pain; 5 = very severe), and instruct the participant to record his/her answer on the form. The same procedure should be used during the 3-month telephone follow-up, except that the examiner should record the responses given by the participant over the phone.

*Participant Reported Outcome Measurement Information System Pain Interference Instrument (PROMIS-PAIN Interference)*

Description: The PROMIS Pain Interference instrument measures the self-reported consequences of pain on relevant aspects of one's life. This includes the extent to which pain hinders engagement with social, cognitive, emotional, physical, and recreational activities. Pain interference also incorporates items probing sleep and enjoyment in life, though the item bank only contains one sleep item. The pain interference short form is generic rather than disease-specific. The 4-item Pain Interference short form will be used in this study. The items assess the degree to which pain has interfered with a variety of cognitive, social and recreational activities over the past seven days. The last item asks participants to rate the frequency with which pain interferes with socializing.

When Administered: PROMIS Pain Interference should be administered to subjects stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at the 2-week, 6-month and 12-month in-person follow-ups, and during the 3-month telephone follow-up.

Order of Administration: The PROMIS Pain Interference should be administered directly after PROMIS Pain Intensity and before the SWLS.

Form: PROMIS Pain Interference Short Form 4a

Staff Responsible: Data collector

Instructions: Provide the participant with the PROMIS Pain Interference response sheet, review the 5-point Likert-style rating scale (e.g. 1 = not at all; 5 = very much) and read the questions aloud. Instruct the participant to record his/her answer on the form. The same procedure should be used during the 3-month telephone follow-up, except that the examiner should record the responses given by the participant over the phone.

*Insomnia Severity Index (ISI)*

*Bastien CH, Vallières A, Morin CM. Validation of the Insomnia Severity Index as an outcome measure for insomnia research. Sleep Med. 2001;2:297–307.*

Description: The Insomnia Severity Index is a standardized assessment instrument designed specifically to assess the severity of both nighttime and daytime components of insomnia. The ISI is a 7-item self-report questionnaire assessing the nature, severity, and impact of insomnia. The recall period is the "two weeks" and the dimensions evaluated are: severity of sleep onset, sleep maintenance, and early morning awakening problems, sleep dissatisfaction, interference of sleep difficulties with daytime functioning, noticeability of sleep problems by others, and distress caused by the sleep difficulties.

When Administered: The ISI should be administered to subjects stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at the 2-week, 6-month and 12-month in-person follow-ups, and during the 3-month telephone follow-up.

Order of Administration: The ISI should be administered after the SWLS and before the PHQ-9.

Form: ISI

Staff Responsible: Data collector

Instructions: Provide the participant with the ISI questionnaire. Read these instructions aloud, **"The Insomnia Severity Index has seven questions. For each question, please CIRCLE the number that best describes your answer. Please rate the CURRENT (i.e. LAST 2 WEEKS) SEVERITY of your insomnia problem(s)."** A 5-point Likert scale is used to rate each item (e.g. 0 = no problem; 4 = very severe problem), yielding a total score ranging from 0 to 28. The total score is interpreted as follows: absence of insomnia (0–7); sub-threshold insomnia (8–14); moderate insomnia (15–21); and severe insomnia (22–28).

**Measures of Participation and Quality of Life**

*Quality of Life After Brain Injury- Overall Scale (QOLIBRI-OS)*

*von Steinbuechel N, Wilson L, Gibbons H, Muehlan H, Schmidt H, Schmidt S, Sasse N, Koskinen S, Sarajuuri J, Höfer S, Bullinger M, Maas A, Neugebauer E, Powell J, von Wild K, Zitnay G, Bakx W, Christensen AL, Formisano R, Hawthorne G, Truelle JL. QOLIBRI overall scale: a brief index of health-related quality of life after traumatic brain injury. J Neurol Neurosurg Psychiatry. 2012 Nov;83(11):1041-7. doi: 10.1136/jnnp-2012-302361.*

Description: The QOLIBRI-OS is a self-report measure that rates level of satisfaction with various aspects of health-related quality of life in individuals who have experienced traumatic brain injury. There are six items that cover areas including: physical condition, cognition, emotions, function in daily life, personal and social life, and current situation and future prospects.

When Administered: The QOLIBRI-OS should be administered to subjects stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at the 2-week, 6-month and 12-month in-person follow-ups, and during the 3-month telephone follow-up.

Order of Administration: The QOLIBRI-OS should be administered directly after the RAVLT 20 minute delayed recall trial and before the PCL-5.

Form: QOLIBRI-OS

Instructions: Provide the participant with a case report form. Read the following instructions: **"We would like to know how satisfied you are with different aspects of your life since your brain injury. For each question please choose the answer which is closest to how you feel now (including the past week) and mark the box with an "X". If you have problems filling out the questionnaire, please ask for help."** Responses to each item are scored 1 ('Not at all') to 5 ('Very').

Control instructions: In the first sentence of the instructions, delete the word, "brain," so the sentence reads, "**We would like to know how satisfied you are with different aspects of your life since your injury**."

*Mayo-Portland Adaptability Inventory 4- Participation Subscale (MPAI-PART)*

*Bohac, D.L., Malec, J. F., et al. (1997). "Factor analysis of the Mayo-Portland Adaptability Inventory structure and validity." Brain Inj 11(7): 469-482.*

Description: The MPAI4-PART (also known as M2PI) represents the Participation Index of the MPAI4 and contains 8 items intended to evaluate the degree of difficulty experienced by people in the post-acute (post-hospital) period following acquired brain injury relative to participation in self-care, social,

recreational and vocational activities. Questions are not anchored to a specific time or life event. It may be completed by the participant, professional staff or a significant other. The type of respondent should be recorded on the CRF.

When Administered: The MPAI4-PART should be administered to participants stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at the 2-week, 6-month and 12-month in-person follow-ups, and during the 3-month telephone follow-up.

Order of Administration: The MPAI4-PART should be administered directly after the NIH Toolbox and before the E-DRS-PI.

Form: MPAI4 M2PI

Instructions: The MPAI4 should be administered directly to the participant unless he/she is unable to respond intelligibly to questions. If the participant cannot respond independently, a significant other should be interviewed. Provide the respondent with a case report form. The examiner should phrase the questions in accord with who is being interviewed. For example, if the participant is being interviewed ask, **"Do you have problems initiating activities without being prompted?"** If a significant other is the respondent, ask **"Does ____ (patients' name) have, problems initiating activities without being prompted?"** Read the following instructions: **"Below each item on your form, circle the number that best describes the level at which you (*or name of participant*) are experiencing problems. Mark the greatest level of problem that is appropriate. Problems that interfere rarely with daily or valued activities, that is, less than 5% of the time, should be considered not to interfere. Write comments about specific items at the end of the rating scale."**

Responses should reflect the current status of the person being rated whether or not conditions other than brain injury are contributing to restrictions in participation. Ratings should reflect how the person is at the time of the evaluation regardless of cause. If medication is required to achieve normal or near normal functioning, this is reflected by rating the item at level 1. Scoring criteria and norms are available by referencing the MAPI Manual in Dropbox (Dropbox\1-TRACK TBI Doc Share\Outcomes Core\Assessments\Administration and Scoring Guidelines).

*Satisfaction with Life Scale (SWLS)*

*Diener, E., Emmons, R. A., Larsen, R. J., & Griffin, S. (1985) The Satisfaction with Life Scale. Journal of Personality Assessment. 49, 71-75.*

Description: The SWLS consists of 5-items designed to assess life satisfaction. Questions are not anchored to a specific time or life event.

When Administered: The SWLS should be administered to subjects stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at the 2-week, 6-month and 12-month in-person follow-ups, and during the 3-month telephone follow-up.

Order of Administration: Administer the SWLS after PROMIS Pain Interference and before the ISI.

Form: SWLS

Instructions: The SWLS should not be completed by proxy, though a proxy can ask questions to the individual and convey answers to an interviewer (for instance, if the respondent cannot be interviewed directly by phone). Provide a SWLS case report form for the participant. Read the following instructions **"On your form, there are five statements that you may agree or disagree with. Using the 1 - 7**

**scale on the form, indicate your agreement with each item by placing the appropriate number on the line preceding that item. The scale options are: 7 - Strongly agree, 6 – Agree, 5 - Slightly agree, 4 - Neither agree nor disagree, 3 - Slightly disagree, 2 – Disagree, 1 - Strongly disagree. Please be open and honest in your responding."**

*12-Item Short Form Survey- Version 2 (SF-12v2)*

*Ware J Jr, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996 Mar;34(3):220-33.*

Description: The SF-12 Health Survey is a shorter version of the SF-36 Health Survey, containing 12 items from the SF-36. The SF-12 is a subjective measure of health and well-being. Items are in a Likert-scale format. There are eight sub-scales, including Physical Functioning, Role Limitations-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Limitations-Emotional, and Mental Health. A physical component score (PCS) and mental component score (MCS) can be computed. The past 4 weeks is used as the reference period for some of the questions. Items are not anchored to a particular life event. High scores indicate better health and function. Version 2 of the SF-12 will be used in TRACK TBI. When administering the SF-12 at the 2-week follow-up, the examiner should read the questions referring to the "past 4 weeks" as they are written on the form. However, the examiner should then clarify that if less than 4 weeks have elapsed since the injury, the subject should answer the question based on the time since injury.

When Administered: The SF-12 v2 should be administered to subjects stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at the 2-week, 6-month and 12-month in-person follow-ups, and during the 3-month telephone follow-up.

Order of Administration: Administer the SF-12 v2 after the RPQ and before the RAVLT 20 minute delayed recall trial.

Form: SF-12 (Version 2)

Instructions: Provide the subjects with the SF-12 v2 case report form. Read the following instructions: **"Answer every question by placing a check mark on the line in front of the appropriate answer. It is not specific for brain injury. If you are unsure about how to answer a question, please give the best answer you can and make a written comment beside your answer."**

**Measures of Psychological Health**

*Posttraumatic Stress Disorder Checklist (PCL-5)*

*Blanchard, E.B., Jones-Alexander, J., Buckley, T.C., & Forneris, C.A. (1996). Psychometric properties of the PTSD Checklist (PCL). Behaviour Research and Therapy, 34, 669-673.*

Description: The PCL-5 is a self-report rating scale intended to assess the 20 DSM-V symptoms of Posttraumatic Stress Disorder. The questionnaire begins by asking the participant whether he/she has ever been exposed to a "very stressful experience," defined as an "actual or threatened death, serious injury, or sexual violence" (interview; page 1). Specific examples (e.g. natural disaster, violent crime, battle field) are provided to help distinguish mild to moderate stressors from those considered severe enough to produce symptoms of PTSD. The participant is then asked to consider the "worst event" experienced and to rate the degree to which he/she has been bothered by problems related to this event over the last month (self-report; page 2).

When Administered: The PCL-5 should be administered to subjects stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at the 2-week, 6-month and 12-month in-person follow-ups, and during the 3-month telephone follow-up.

Order of Administration: The PCL-5 should be administered directly after the QOLIBRI-OS and before the BSI-18.

Form: PCL-5

Instructions: Begin by asking the participant to identify the worst event they have experienced after reading the following instructions: **"This questionnaire asks about problems you may have had after a very stressful experience involving actual or threatened death, serious injury, or sexual violence. It could be something that happened to you directly, something you witnessed, or something you learned happened to a close family member or close friend. Some examples are a serious accident in which you may have been injured; fire; disaster such as a hurricane, tornado, or earthquake; physical or sexual attack or abuse; war; homicide; or suicide.**

**First, please answer a few questions about your worst event, which for this questionnaire means the event that currently bothers you the most. This could be one of the examples above or some other very stressful experience. Also, it could be a single event (for example, a car crash) or multiple similar events (for example, multiple stressful events in a war-zone or repeated sexual abuse). Have you experienced any serious events like this? If yes, can you please briefly tell me what the event(s) was/were? (Record here_____). If you have not experienced a very stressful event like the ones described, identify the most stressful event you have ever experienced, and then complete the questionnaire using that event as your reference for the remaining questions about how much that event has bothered you."**

After completing page 1, read the following instructions: **"Keeping this worst event in mind, read each of the problems on the next page and then circle one of the numbers to the right to indicate how much you have been bothered by that problem *in the past month*."** Note that at the 2-week follow-up, if the participant states that the incident for which they were enrolled in the study, or some other incident occurring less than 1 month ago, is the 'worst event', they should anchor their responses to this event rather than "in the past month".

Scoring: For each item, ensure that the participant circles the number that represents the corresponding severity rating (e.g. 0 = not at all; 4 = extremely). Ensure that all items have been completed by the participant.

*Brief Symptom Inventory 18 (BSI-18)*

*Derogatis, Leonard R., and Nick Melisaratos." The Brief Symptom Inventory: an introductory report." Psychological medicine 3 (1983): 595-605.*

Description: The Brief Symptom Inventory 18 measures psychological distress and psychiatric disorders in medical and community populations. It is an 18-item instrument with equal representation from the BSI primary symptom dimensions of Somatization, Depression, and Anxiety. The past 7 days is used as the reference period for the questions. Items are not anchored to a particular life event.

When Administered: The BSI-18 should be administered to subjects stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at the 2-week, 6-month and 12-month in-person follow-ups, and during the 3-month telephone follow-up.

Order of Administration: The BSI-18 should be administered directly after the PCL-5 and before the Participant/Surrogate Interview.

Form: BSI-18

Instructions: The BSI-18 should be explained to the respondent in a positive and unhurried manner. After explaining the test, read the instructions "The BSI-18 consists of a list of problems people sometimes have. Read each one carefully and circle the number of the response that best describes HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST 7 DAYS INCLUDING TODAY. Circle only one number for each problem (0 1 ② 3 4). Do not skip any items. If you change your mind, draw an X through your original answer and then circle your new answer (0 1 ⊗ 3 ④). Read the example before beginning. If you have any questions, please ask them now."

*If the participant answers ≥1 (a little bit) on item # 17 (i.e. "thoughts of ending your life"), complete the "Columbia Suicide Severity Rating Scale," and follow the Protocol for managing suicidal ideation and intent.*

BSI-18 Scoring Procedures:

- If the respondent's age is less than 18, STOP. Do not administer the test. The BSI-18 norms cannot be used with individuals younger than 18.
- On the answer sheet, record the value (0-4) of each circled response on the line to the right of each item.

*Participant Health Questionnaire- 9 (PHQ-9)*

*Kroenke K, Spitzer R, Williams W. The PHQ-9: Validity of a brief depression severity measure. JGIM, 2001, 16: 606-616.*

Description: The Participant Health Questionnaire 9 is a standardized assessment instrument designed to screen, diagnose, monitor, and measure the severity of depression.

When Administered: The PHQ-9 should be administered to subjects stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at the 2-week, 6-month and 12-month in-person follow-ups, and during the 3-month telephone follow-up.

Order of Administration: The PHQ-9 should be administered after the ISI and is the last measure in the CAB unless it is deemed necessary to administer the C-SSRS.

Form: PHQ-9

Instructions: Provide the participant with the PHQ-9 questionnaire. Read these instructions, "Over the last *2 weeks*, how often have you been bothered by any of the following problems? (Use a check mark to indicate your answer)." Read the questions aloud, review the 4 response options (e.g. 0 = not at all; 3 = nearly every day) and instruct the participant to answer for him/herself. If the participant cannot physically answer the questions on their own, have them tell you their answer and mark the PHQ-9 CRF for them.

*If the participant answers ≥1 (several days) on item # 9 (i.e. "thoughts that you would be better off dead, or of hurting yourself"), complete the "Columbia Suicide Severity Rating Scale," and follow the Protocol for managing suicidal ideation and intent.*

*Columbia Suicide Severity Rating Scale (C-SSRS)*

*Posner, K., Brown, G.K., Stanley, B., Brent, D.A., Yershova, K.V., Oquendo, M.A., Currier, G.W., Melvin, G., Greenhill, L., Shen, S., & Mann, J.J. "The Columbia- Suicide Severity Rating Scale (C-SSRS): Initial Validity and Internal Consistency Findings from Three Multi-Site Studies with Adolescents and Adults." American Journal of Psychiatry, 2011; 168:1266-1277.*

Description: The Columbia Suicide Severity Rating Scale is a standardized assessment instrument designed to assess the presence and severity of suicidal ideation and behavior, identify those at risk and track response to treatment. Four constructs are measured. The first is the severity of ideation (hereafter referred to as the "severity subscale"), which is rated on a 5-point ordinal scale in which 1=wish to be dead, 2=nonspecific active suicidal thoughts, 3=suicidal thoughts with methods, 4=suicidal intent, and 5=suicidal intent with plan. The second is the intensity of ideation subscale (hereafter referred to as the "intensity subscale"), which comprises 5 items, each rated on a 5-point ordinal scale: frequency, duration, controllability, deterrents, and reason for ideation. The third is the behavior subscale, which is rated on a nominal scale that includes actual, aborted, and interrupted attempts; preparatory behavior; and non-suicidal self-injurious behavior. And the fourth is the lethality subscale, which assesses actual attempts; actual lethality is rated on a 6-point ordinal scale, and if actual lethality is zero, potential lethality of attempts is rated on a 3-point ordinal scale.

When Administered: The C-SSRS should be administered to participants stratified to the Comprehensive Assessment and Comprehensive Assessment + MRI cohorts at the 2-week, 6-month and 12-month in-person follow-ups, and during the 3-month telephone follow-up **only if the participant screens positive for suicidal ideation/behavior on the PHQ-9 and/or BSI-18 (i.e. scores ≥ 1 on question 9 or 17, respectively)**. The C-SSRS must be completed by the participant- significant others cannot be interviewed in place of the participant. If the participant is unable to provide responses, the measure should not be administered. The examiner should indicate that the participant was untestable and enter the appropriate test completion code on the case report form.

*Note: Specialized training in use of the C-SSRS is necessary before the examiner administers the scale. Training requires viewing of videos developed by the authors of the scale. The videos can be accessed at http://c-ssrs.trainingcampus.net/uas/modules/trees/windex.aspx. Register on the RFMH website. Go to the "My Activities" link on the horizontal bar at the top of the screen. Select RFMH-Z01-Admin Training for the Columbia Suicide Severity Rating Scale (C-SSRS) Screener Version AND RFMH-102 - The C-SSRS Training – English-International - V.1.1 from the pre-populated list below. There is also a Spanish version that sites that are enrolling Spanish speakers can complete. The first ("Screener") is the standard training and the second ("English International") are case studies that will be helpful for the concepts reviewed. Please submit your training certificates to Dr. Sabrina Taylor at sabrina.taylor@ucsf.edu.*

Order of Administration: The C-SSRS should be administered directly after the PHQ-9, if required, and is the final test in the CAB.

Form: C-SSRS

Instructions: Administer only if the participant screens for suicidal ideation/behavior on the PHQ-9 and/or BSI-18. Unlike the other self-report measures, the examiner should read the C-SSRS questions *and* record the participant's responses. This approach is required because the questionnaire includes "skip rules" that require the examiner to see the participant's responses to determine which additional items are to be administered. For example, if the answer to questions 1 and 2 is "no," the remaining questions in this section are skipped and the next section on suicidal behavior is administered. But, if the participant answers "yes" to question 2, questions 3, 4, and 5 are administered before progressing to the next section on intensity of suicidal ideation. The "Baseline-Screening" version should be used

at the 2-week follow-up and the "Since Last Visit" version should be administered at the 6 and 12-month follow-up visits. Read the questions aloud and instruct the participant to mark the record form by selecting "yes" or "no" for each item. If the participant cannot record their answer on their own, the examiner can mark the C-SSRS CRF for them. Note that each question is anchored to two time points. One column is marked "Lifetime" and the other, "Last __month(s)." The respondent should record his/her response to both time points before proceeding to the next question. Under the "Lifetime" column, the respondent should use their entire lifetime as their frame of reference for answering the question. For the "Last _ month(s) column, 1 month should be used as the frame of reference. The exception to this is the 2-week follow-up, for which a 14-day frame of reference should be used. Upon completion of the interview, the C-SSRS total and subscale scores should be recorded on the C-SSRS case report form.

Protocol for Managing Suicidal Ideation and Intent

If the participant endorses either CSSRS question #1 (i.e. "*Have you wished you were dead or wished you could go to sleep and not wake up?")* or #2 (i.e. "*Have you actually had any thoughts of killing yourself?),* proceed with administration of the remaining items as directed in the instructions. After completing all items on the CSSRS, follow one of the procedures described below.

Scenario 1: Participant responds "no" to question 2 on C-SSRS ("Have you actually had any thoughts of killing yourself?")

- Empathize with how hard things have been for the participant and let him/her know that it is not unusual for people to have these thoughts when they have experienced TBI. Encourage them to talk to a family member or friend when they feel this way. Also provide them with a crisis line number and encourage them to phone if they ever start thinking about actually killing themselves. Proceed with the study protocol.

Scenario 2: Participant responds "yes" to question 2 on C-SSRS ("Have you actually had any thoughts of killing yourself?") AND answers "no" to question 3 ("Have you been thinking about how you might kill yourself?")

- Empathize with how hard things have been for the participant and let him/her know that it is not unusual for people to have these thoughts when they have experienced TBI. Encourage them to talk to a family member or friend when they feel this way. Also provide them with a crisis line number and encourage them to phone if they ever start thinking about actually killing themselves. Proceed with the study protocol.

Scenario 3: Participant responds "yes" to question 3 on C-SSRS ("Have you been thinking about how you might kill yourself?") AND answers "no" to question 4 ("Have you had these thoughts and had some intention of acting on them?").

- Discuss a safety plan with the participant. If you are meeting with the participant in person, have them complete the safety plan themselves, providing guidance as necessary. Then have the participant sign it and ask the study physician or a licensed psychologist on the team to review the plan with them. Provide them with the crisis line information by writing it on the

safety plan. If you are talking with the person by phone, go over the safety plan, asking them to generate responses to the items, while providing guidance as necessary. Record their responses and then ask the study physician or a licensed psychologist on the team to review the plan with them. Send them a copy by mail, provide the contact information for the crisis line verbally over the phone and write it on the safety plan before mailing.

Scenario 4: Participant responds "yes" to question 3 on C-SSRS ("Have you been thinking about how you might kill yourself?") AND either answers "yes" to question 4 ("Have you had these thoughts and had some intention of acting on them?") or is equivocal regarding whether they intend to act on their thoughts.

- Ensure that the participant is safe at the moment. This means that they are not in imminent danger of harming themselves and do not have guns, knives or other weapons available to use. If you cannot deem that they are safe, ask their permission to speak with a family member who is with them. Tell the family member that they should stay with the participant and should make sure that they are safe, provide them with the crisis line number, advise them to take the person to an emergency room if possible, and advise them to call 911 if they fear that they cannot stop the person from hurting themselves and cannot talk them into going to the emergency room. If there is no family member present, or they refuse to have you speak with one, and you cannot deem that they are safe, maintain them on the line and ask the study physician, another research team member or an administrative assistant to call 911 and ask that the police visit the participant at their current location. Meanwhile, ask the participants' permission to connect them to a crisis line so that they can talk with someone who is trained to help them through the crisis. If they agree, connect them to the crisis line.

*Note: Occasionally, someone may withhold permission for you to transfer them to a crisis line. If this refusal appears to be due to fear, uncertainty, or embarrassment, then talk them through the reasons for the crisis line and ask their permission again. If they still refuse, or if they appear to simply want to stay on the line talking with you, tell them that for their own safety, you need to connect them to the crisis line. Ask them to stay on hold while you dial the crisis line. Make sure that they have your telephone number so that they can call you back in case you are disconnected. You may call them back if you are disconnected. If you cannot reach them, and you think they are in imminent danger of harming themselves, then call 911 and ask the police to visit the person at their current location.*

The same protocol can be applied to a person who endorses suicidal ideation and intent during an on-site assessment. In this case, have them call the crisis line from a nearby office.

REMEMBER TO DOCUMENT EACH STEP THAT YOU PERFORM, HAVE THE SITE PI OR HIS/HER DESIGNEE (EG, STUDY PHYSICIAN, PSYCHOLOGIST) REVIEW THE SAFETY PLAN AND PLACE IT IN THE PARTICIPANTS' RESEARCH FILE.

Process for connecting on-line telephone participant to crisis line:

While on the phone with the participant, ask them to hold while you connect them to the crisis line (or use the conference-calling feature, if available):

Crisis Line #: 1-800-273-TALK (8255) National Suicide Prevention Lifeline
1-888-628-9454 (Spanish)

Be sure the participant has been connected to a crisis counselor before hanging up.

## Completion of Case Report Forms, Data Entry and Data Quality Monitoring

The examiner should fill out the paper case report form as each test or questionnaire is being administered. Ensure that all fields on the CRF, including the date (mm/dd/yyyy), time (in military notation [hh:mm]), and participant ID#, have been completed. The data should be transferred from the paper CRF to the electronic CR, which is housed in QuesGen, and submitted as soon as possible and no longer than two business days from the date the assessment is completed. If the assessment battery cannot be completed in one day, the data obtained prior to discontinuation of the assessment should be entered into QuesGen within two business days of the date of discontinuation, and the remaining data should be entered within two business days of the date the assessment is completed. The data collector should "Save" the data each time data entry is performed. Data entered and saved in QuesGen can be changed until the data collector presses the "Submit" button. At this point, the CRF will be locked and further changes cannot be made directly by study staff. If changes are necessary following data submission, the data collector should contact QuesGen for further assistance.

## Protocol for Sharing Outcome Data with Participants

Outcomes data can be shared with participants only after study completion (i.e. after completion of the 12 month follow-up). It should be noted that these results should only be released to subjects who retain capacity or their legal guardian. If the participant or guardian requests to see his or her data after the 12 month follow-up, the data collector should advise the study PI that ***a written*** request has been made, and the study PI should ensure that the results are communicated only by a licensed psychologist (neuropsychologist) who is familiar with the TRACK TBI outcome assessment battery, and has been authorized by the site PI to serve in this capacity. This consultation can be completed in person or over the telephone. If a licensed psychologist is not available, the data should be released in the form of raw data with the name of the measure and a score without any interpretation. A disclaimer statement must be included in the released records (i.e. "These data are not meant to replace diagnostic testing/evaluation that would be ordered by a personal physician. We cannot interpret the data or provide recommendations as the data we collect is meant for research purposes only.") Test record sheets should not be released under any circumstances due to risk of copyright violation and test invalidation.

## Guidance for Administration of TRACK-TBI Outcome Battery in Orthopedic Controls

### Background

TRACK-TBI sites will begin enrolling patients who have sustained extracranial trauma but no evidence of TBI as study controls.* Controls will be enrolled into the CA-MRI cohort for follow-up and will drop down to CA at 2-weeks if they are unable to complete the MRI visit. A total of 300 controls will be enrolled study-wide from the 3 clinical care path cohorts (ED, ADM, ICU). Controls must meet the following criteria:

1) Age >17

2) Documented evidence of orthopedic trauma defined by an Abbreviated Injury Score of <4 (not life threatening extremity) for their extremity and/or pelvis injury.
3) Meets all other TRACK-TBI inclusion and exclusion criteria (see section 6.1 of the Clinical SOP) except that the requirement of having undergone a CT or MRI in the ED for suspected head injury does not apply. Control subjects who undergo "head to toe" imaging studies remain eligible for enrollment as long as the results are negative for TBI.

**Note that TBI will be ruled out for the current injury by interviewing potential controls about loss or disturbance of consciousness, and post-traumatic or retrograde amnesia).*

**Instructions**

Orthopedic control subjects will undergo the same battery of clinical outcome measures as the TBI subjects, and follow-ups will be conducted using the same assessment windows currently employed for the TBI group. Because ortho control subjects, by definition, have not sustained brain injury and many of our measures were designed for use in patients with TBI, some adjustments to the test administration procedures will be necessary. In some cases, it may be necessary to explain why the subject is being asked about or assessed for brain injury. The examiner can explain that this is simply a routine part of participation in the study and does not imply that there is any concern or suspicion of brain injury. If adjustments to the test administration procedures are required for the fluidity of the battery administration (not all assessments need to be modified), information on these adjustments can be found within the "Control Instructions" section of each of the measures within the SOP. The measures that have been adjusted for controls are: Assessment of post-traumatic amnesia (PTA) duration, Revised Glasgow Outcome Scale- Extended (R-GOSE), Expanded Disability Rating Scale-Post-acute Interview (E-DRS-PI), Participant/Surrogate Interviews, and Quality of Life After Brain Injury- Overall Scale (QOLIBRI-OS).

When indicated, use the Test Completion Codes for the performance-based measures to capture extraneous factors that may prevent, influence or invalidate administration of specific measures.

Please make note of any problems that may arise when administering the outcome assessment battery to the ortho control group and forward a brief description of the problem to the Outcome Core Leads, Drs. Giacino (jgiacino@mgh.harvard,edu) and Dikmen (dikmen@u.washington.edu), by email.