

TRACK-TBI

Transforming Research and Clinical Knowledge
in Traumatic Brain Injury

International Traumatic Brain Injury Research Initiative

**Standard Operating Procedures for
Outcome Assessment
Version 4**

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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.

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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 \pm 4 days Outcomes: \pm 3 days of 2-week MRI
CA/BA Cohorts	Outcomes: 14 days post-injury \pm 4 days
3 Month Telephone Follow-up Assessment Window	
All Cohorts	Outcomes: 90 days post-injury \pm 7 days
6 Month Follow-up Assessment Windows	
CA + MRI Cohort	MRI: 180 days post-injury \pm 14 days Outcomes: \pm 14 days of 6-month MRI BTACT: \pm 7 days of Outcomes (but not on the same day)
CA/BA Cohorts	Outcomes: 180 days post-injury \pm 14 days BTACT: \pm 7 days of Outcomes (but not on the same day)
12 Month Follow-up Assessment Window	
All Cohorts	Outcomes: 360 days post-injury \pm 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 Gabriela Satris (Gabriela.Satris@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.

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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	<ul style="list-style-type: none"> Assessment of speech intelligibility Galveston Orientation and Amnesia Test (Standard, Written, and Modified GOAT) Post-traumatic amnesia (PTA) assessment 	2m 5m 2m	2W, then as needed	N/A
Abbreviated Battery (AAB) (60-85 minutes- includes screening)				
Participant/Surrogate Interviews	<ul style="list-style-type: none"> Sections: <ul style="list-style-type: none"> Demographic Variables Vocational History Pre-morbid medical history Prior TBI screen Alcohol Use Disorders Identification Test (AUDIT-C) 3-Item Drug Use Interview 	15 min	2W, 3M (T), 6M, 12M	N/A
Consciousness and Basic Cognition	<ul style="list-style-type: none"> Confusion Assessment Protocol (CAP) Coma Recovery Scale Revised (CRS-R) 	15m 15-30m	2W, 6M, 12M	N/A
Global Outcome	<ul style="list-style-type: none"> Revised-Glasgow Outcome Scale Extended (RGOSE) Expanded Disability Rating Scale Post-Acute Interview (E-DRS-PI) 	8m 5-15m	2W, 3M (T), 6M, 12M	RGOSE only 2W (T), 3M (T), 6M (T), 12M (T)
Comprehensive Assessment Battery (CAB) (136-148 minutes- includes screening; excludes BTACT)				
Global Outcome	<ul style="list-style-type: none"> Revised-Glasgow Outcome Scale Extended (RGOSE) Expanded Disability Rating Scale Post-Acute Interview (E-DRS-PI) 	8m 5-15m	2W, 3M (T), 6M, 12M	N/A
Participant/Surrogate Interviews	<ul style="list-style-type: none"> Sections: <ul style="list-style-type: none"> Demographic Variables Vocational History Pre-morbid medical history Prior TBI screen Alcohol Use Disorders Identification Test (AUDIT-C) 3-Item Drug Use Interview 	15 min	2W, 3M (T), 6M, 12M	N/A
Cognition	<ul style="list-style-type: none"> Rey Auditory Verbal Learning Test II (RAVLT) Trail Making Test (TMT) Wechsler Adult Intelligence Scale IV Processing Speed Index (WAIS-IV PSI) NIH Toolbox Cognitive Battery Brief Test of Adult Cognition by Telephone (BTACT) 	15m 5m 4m 30m 20m	2W, 6M, 12M ----- 6M (T)	N/A
Post-Concussive/TBI-Related Symptoms	<ul style="list-style-type: none"> Rivermead Post-Concussion Questionnaire (RPQ) Participant Reported Outcome Measurement Information System Pain Intensity and Interference Instruments (PROMIS-PAIN) Insomnia Severity Index 	6m 5m 3m	2W, 3M (T), 6M, 12M	N/A
Participation and Quality of Life (QoL)	<ul style="list-style-type: none"> Quality of Life After Brain Injury- Overall Scale (Qolibri-OS) Mayo-Portland Adaptability Inventory- (MPAI4-PART) Satisfaction With Life Scale (SWLS) SF-12 Version 2 	2m 5m 3m 3m	2W, 3M (T), 6M, 12M	N/A
Psychological Health	<ul style="list-style-type: none"> PTSD Checklist (PCL-5) Brief Symptom Inventory 18 (BSI18) Participant Health Questionnaire- 9 (PHQ-9) Columbia Suicide Severity Rating Scale (C-SSRS)* <p>(*Only required if ≥ 1 on the PHQ-9 or the BSI-18)</p>	6m 6m 5m 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

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), 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 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\Assessments\CRF Binders\CRF Binder](#)). 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, another document named CRF_Training_Stimuli_TMT_WAIS, located in the same CRF Binder folder in Dropbox, should be printed before recording the video as it contains the stimuli required to administer the Trails and WAIS assessments in the CAB. Helpful vimeo videos of the administration of all of the measures can be found on Dropbox ([Dropbox\1-TRACK TBI Doc Share\Outcomes Core\Example Battery Administrations for Certification](#)).

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After recording the administration of the batteries, mail the tape containing the Screening Protocol/ AAB/Global Outcome Measures and email the paper CRFs to:

Dr. Sabrina Taylor
Spaulding Rehabilitation Hospital
300 First Avenue, #3227
Charlestown, MA 02129
617-952-6392
srtaylor@partners.org

After recording the administration of the batteries, mail the tape containing the CAB/BTACT and email the paper CRFs to:

Kim Boase
215-214th St SE
Bothell, WA 98021
206-744-8323
kboase@u.washington.edu

Do not post any videos containing test material to publically accessible websites such as YouTube. However, if you would like to send your recordings electronically please contact Gigi Satris Gabriela.Satris@ucsf.edu 415-206-4413 and she will set up a secure link via our Dropbox account to share these files.

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

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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

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“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

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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

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	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.

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

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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.

When it is necessary to assign a Test Completion Code for a given test, the examiner should record the designated code(s) on the corresponding case report form.

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

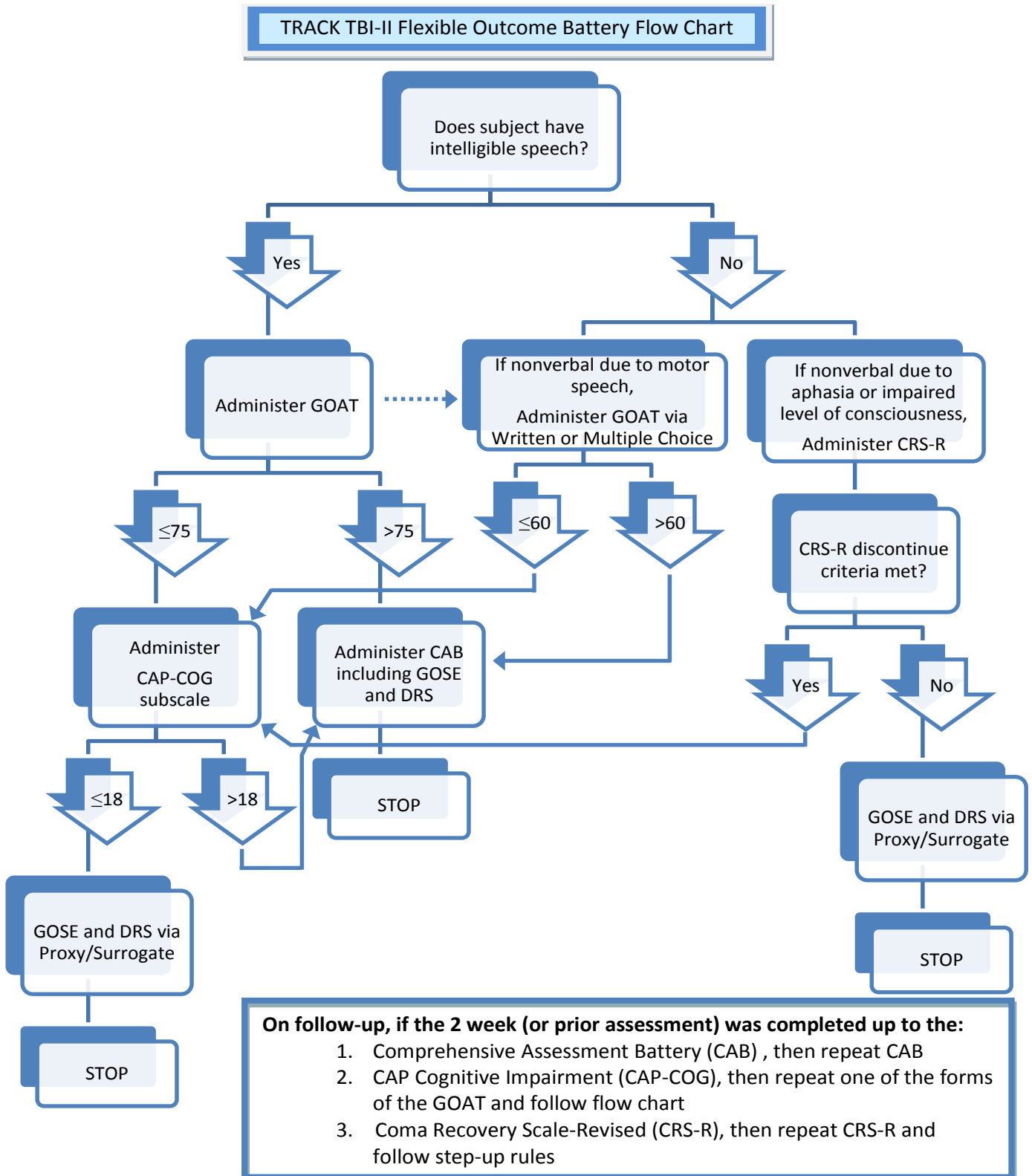
Overview

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
<u>Screening Measures for Abbreviated and Comprehensive Batteries</u> (5 - 7 min) <ol style="list-style-type: none"> 1. Assessment of Speech Intelligibility 2 min 2. GOAT 5 min 3. Post-traumatic amnesia (PTA) assessment 2 min
<u>Abbreviated Battery</u> (43 - 83 min) <ol style="list-style-type: none"> 4. Participant/Surrogate Interview (Living Situation, Follow-up Care, Return to Work) (15 min) 5. CRS-R 15 - 30 min * 6. CAP-COG 15 min * 7. R-GOSE 8 min 8. E-DRS-PI 5-15 min
<u>Comprehensive Battery</u> (58 min) <ol style="list-style-type: none"> 9. R-GOSE 8 min 10. RAVLT (5 learning trials, interference list with recall, immediate recall first list) 15 min 11. TMT (A&B) 5 min 12. WAIS-IV PSI (Coding and Symbol Search) 4 min 13. RPQ 6 min 14. SF-12 (Version) 3 min 15. RAVLT 20 Minute Delayed Recall 3 min 16. Qolibri-OS 2 min 17. PCL-5 6 min 18. BSI-18 6 min (if ≥ 1, proceed to the C-SSRS)
19. <u>Participant/Surrogate Interview</u> (Living Situation, Follow-up Care, Return to Work, Substance Abuse) 15 min
<u>Break</u>

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

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).

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.

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

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obtained on the GOAT-M are 88, therefore, the cut-off for impairment is ≤ 60 because the GOAT-M omits questions 4 and 5 (which total 20 error points).

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.

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.

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

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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.

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.

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

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.

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.

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

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Variables” section of the eCRF and code a TCC of 2.2 (Test attempted not completed due to non-neurological/physical reasons).

- If the CRS-R or CAP are attempted but not completed due to agitation, the TCC code should be 2.1 (Test attempted not completed due to cognitive/neurological 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]

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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.

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.

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.

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

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Dimensional Change Card Sort Test). Each site will need a laptop, monitor, speakers, keyboard and mouse for the administration of the cognitive battery.

Brief Test of Adult Cognition by Telephone (BTACT)

Description: The BTACT is a battery of measures designed to assess cognitive status over the telephone.

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](https://doi.org/10.1007/BF00868811). PMID [8551320](https://pubmed.ncbi.nlm.nih.gov/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

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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.

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”.

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.

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.

Measures of Participation and Quality of Life

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

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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.

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.

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.

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.

Measures of Psychological Health

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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).

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.

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.

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.

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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.

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 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

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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 (igiacino@mg.harvard.edu) and Dikmen (dikmen@u.washington.edu), by email.