



NINDS Common Data Element (CDE) Project

Traumatic Brain Injury Version 3.0

Internal Review / Public Review

Performance-based Measure Subgroup Materials

Subgroup Summary

Instruments

- Bedside Western Aphasia Battery Revised
- Beery-Buktenica Developmental Test of Visual-Motor Integration (Beery VMI)
- Brief Visuospatial Memory Test Revised (BVM-T-R)
- Comprehensive Assessment of Spoken Language, Second Edition (CASL-2)
- Controlled Oral Word Association Test (COWAT) Subtest of the Multilingual Aphasia Examination (MAE)
- Functional Gait Assessment
- Functional Independence Measure (FIM)
- Functional Independence Measure (FIM) - Motor Subscale
- Grooved Pegboard Test
- Gross Motor Function Measure (GMFM-88, GMFM-66)
- High-Level Mobility Assessment Tool (HiMAT)
- Mini-Balance Evaluation Systems Test (Mini-BESTest)
- Modified Clinical Test of Sensory Interaction on Balance (mCTSIB)
- NIH Toolbox Motor Battery
- NIH Toolbox Odor Identification Test (OIT)
- Peabody Picture Vocabulary Test 5th Edition (PPVT-5)
- Pediatric Evaluation of Disability Inventory (PEDI) Mobility Subscale
- Processing Speed Index of the Wechsler Adult Intelligence Scale-Fifth Edition (WAIS-5)
- SCAN-A and SCAN-C Auditory Processing Disorders Subtests
- Symbol Digit Modalities Test
- Victoria Symptom Validity Test (VSVT)
- Wide Range Assessment of Memory and Learning, Third Edition (WRAML-3)

Case Report Forms

- Death
- Hearing
- Neurological Assessment: Glasgow Coma Scale (GCS) and Pupils
- Neurological Assessment: LOC, PTA, and AOC
- Neurological Assessment: TBI Symptoms and Signs
- Post Discharge Status
- Post-Traumatic Epilepsy Screening Form
- Screening Tools
- Study Discontinuation/Completion

Instruments Pending Review

- Automated Neuropsychological Assessment Metrics (ANAM)
- Bayley Scales of Infant Development (Bayley-4, BSID)



- California Verbal Learning Test - Children (CVLT-C)
- Children's Orientation and Amnesia Test (COAT)
- Color-Word Interference Test Delis-Kaplan Executive Function System (D-KEFS)
- Conner's Continuous Performance Test III
- Contingency Naming Test (CNT)
- Delis-Kaplan Executive Function System (D-KEFS)
- Functional Assessment of Verbal Reasoning and Executive Strategies-Student Version (SFAVRES)
- Galveston Orientation and Amnesia Test (GOAT)
- Goldman Fristoe Test of Articulation 3 (GFTA-3)
- JFK Coma Recovery Scale- Revised
- Letter-Number Sequencing Subtest
- Medical Symptom Validity Test (MSVT)
- National Adult Reading Test (NART)
- NIH Toolbox Cognitive Battery
- NIH Toolbox Dynamic Visual Acuity Test (DVA)
- NIH Toolbox Regional Taste Intensity Test
- NIH Toolbox Sensory Battery
- NIH Toolbox Standing Balance Test (SBT)
- Processing Speed Index of the Wechsler Intelligence Scale for Children-V/ Wechsler Preschool and Primary Scale of Intelligence (WISC-V/WPPSI-IV)
- Random Gap Detection Test (RGDT)
- Rey Auditory Verbal Learning Test (RAVLT)
- Shape School
- Test of Everyday Attention for Children, Second Edition (TEA-Ch2)
- Test of Language Competence Extended (TLC-E)
- Test of Memory and Learning Revised (TOMAL-2)
- Test of Memory Malinger (TOMM)
- Test of Premorbid Functioning (TOPF)
- Test of Strategic Learning (TOSL)
- The Combat Exposure Scale (CES)
- The Eriksen Flanker Test
- The National Health and Nutrition Examination Chemical Senses-Taste and Smell Questionnaire (NHANES CSQ)
- Time Compressed Sentence Test (TCST)
- Trail Making Test (TMT), Delis-Kaplan Executive Function System (D-KEFS)
- TRAILS-P
- Verbal Fluency Test, Delis-Kaplan Executive Function System (D-KEFS)
- Veterans Rand 36-Item Health Survey (VR-36)
- Voice Handicap Index (VHI)
- Wechsler Abbreviated Scale of Intelligence - Second Edition (WASI-II)
- Wechsler Abbreviated Scale of Intelligence (WASI II); 2 Subtest Version
- Wechsler Adult Intelligence Scale-Fifth Edition (WAIS-5) - Digit Span Subtest
- Wechsler Block Design
- Word Memory Test
- Word Reading Subtest of the Wide Range Achievement Test (WRAT-5)
- Words-In-Noise Test (WIN)



Instruments to be Reassigned to Another Subgroup

- Behavior Rating Inventory of Executive Function - Second Edition (BRIEF-2)
- Dizziness Handicap Inventory (DHI)
- Functional Independence Measure for Children (WeeFIM) - Motor Subscale
- Neurological Outcome Scale for Traumatic Brain Injury (NOS-TBI)
- NIH Toolbox Hearing Handicap Inventory Supplemental Measure (HHI-SM)
- Patient-Reported Outcome Measurement Information System (PROMIS) Mobility Domain
- Patient-Reported Outcomes Measurement Information System (PROMIS) Upper Extremity Domain
- Tinnitus Functional Index (TFI)
- Tinnitus Handicap Inventory (THI)



NINDS CDE Project Traumatic Brain Injury Version 3.0 Performance-based Measures Subgroup Summary

The NINDS TBI v3.0 Common Data Element (CDE) Performance-based Measures Subgroup reviewed and updated CDEs through a process informed by available clinical research.

Performance-based measures are diverse, and they can be used in a variety of ways in TBI research. In people with severe or catastrophic traumatic brain injuries, they can be used as endpoints, such as documenting the spectrum from disorders of consciousness to death. For TBI research involving any severity of injury, across the lifespan, they can be used to identify health problems and to quantify the severity of those problems. They are also used to monitor changes in functioning over time due to natural recovery or in response to treatment and rehabilitation. Measures of physical, sensory, language, and cognitive functioning were included. The subgroup did not focus on reviewing measures of psychiatric or psychological status, post-concussion symptoms, social functioning, occupational functioning, or quality of life.

The subgroup evaluated dozens of screening measures, tests, and test batteries that can be used to evaluate different aspects of motor, sensory, language, and cognitive functioning. Measures for infants and toddlers, children, adolescents, adults, and older adults were included. The subgroup expanded their review to include measures of balance and mobility that were not included in this subgroup in the NINDS TBI v2.0 CDEs. The content, tests, and measures reviewed by the subgroup do not overlap with other subgroups.



Summary of Recommendations

Subdomain	Instrument/CRF Name	Classification
Deafness and Communication Disorders	NIH Toolbox Odor Identification Test (OIT)	Pending Classification
	SCAN-A and SCAN-C Auditory Processing Disorders Subtests	Pending Classification
Effort/Symptom Validity	Victoria Symptom Validity Test (VSVT)	Pending Classification
End Points	Death	Supplemental – Highly Recommended; Supplemental
	Post Discharge Status	Supplemental – Highly Recommended
Language	Bedside Western Aphasia Battery Revised	Pending Classification
	Comprehensive Assessment of Spoken Language, Second Edition (CASL-2)	Pending Classification
	Peabody Picture Vocabulary Test 5th Edition (PPVT-5)	Pending Classification
Neuropsychological Impairment	Beery-Buktenica Developmental Test of Visual-Motor Integration (Beery VMI)	Pending Classification
	Brief Visuospatial Memory Test Revised (BVM-T-R)	Pending Classification
	Controlled Oral Word Association Test (COWAT) Subtest of the Multilingual Aphasia Examination (MAE)	Pending Classification
	Grooved Pegboard Test	Pending Classification
	Processing Speed Index of the Wechsler Adult Intelligence Scale-Fifth Edition (WAIS-5)	Pending Classification
	Symbol Digit Modalities Test	Pending Classification
	Wide Range Assessment of Memory and Learning, Third Edition (WRAML-3)	Pending Classification
	Study Discontinuation/Completion	Supplemental
Physical Function	Functional Gait Assessment	Pending Classification
	Functional Independence Measure (FIM)	Pending Classification
	Functional Independence Measure (FIM) - Motor Subscale	Pending Classification
	Gross Motor Function Measure (GMFM-88, GMFM-66)	Pending Classification
	High Level Mobility Assessment Tool (HiMAT)	Pending Classification
	Mini-Balance Evaluation Systems Test (Mini-BESTest)	Pending Classification
	Modified Clinical Test of Sensory Interaction on Balance (mCTSIB)	Pending Classification
	NIH Toolbox Motor Battery	Pending Classification
	Pediatric Evaluation of Disability Inventory (PEDI) Mobility Subscale	Pending Classification



Subdomain	Instrument/CRF Name	Classification
Physical/Neurological Examination	Hearing	Pending Classification
	Neurological Assessment: Glasgow Coma Scale (GCS) and Pupils	Pending Classification
	Neurological Assessment: LOC, PTA, and AOC	Pending Classification
	Neurological Assessment: TBI Symptoms and Signs	Pending Classification
	Post-Traumatic Epilepsy Screening Form	Pending Classification
	Screening Tools	Supplemental

Instruments Reviewed and Not Recommended for v3.0

Instrument Name	TBI v2.0 Classification	Instrument Selection Criteria Not Met
Balance Error Scoring System Modified (BESS-Modified)	Supplemental	Broadly validated with demonstrated utility? Reliable?
Bruininks Oseretsky Test of Motor Proficiency-2 (BOT-2) Bruininks Oseretsky Test of Motor Proficiency-3 (BOT-3)	Supplemental	Reliable? Low burden to participants and investigators?
Caregiver Unintelligible Speech Rating Scale	Supplemental	Well-established, broadly applicable to the intended population (e.g., adult and/or pediatric), and generally accepted by the scientific community? Broadly validated with demonstrated utility? Reliable? Standard measurement protocols exist? Low burden to participants and investigators? Crosscutting relevance for population groups as well as diseases and conditions? Rural vs. Urban (Feasibility of Acquisition)? International harmonization (International applicability)?
Clinical Evaluation of Language Fundamentals - Fifth Edition (CELF-5)	Supplemental	Broadly validated with demonstrated utility? Specific? Reliable? Low burden to participants and investigators? Crosscutting relevance for population groups as well as diseases and conditions? Rural vs. Urban (Feasibility of Acquisition)? International harmonization (International applicability)?



Instrument Name	TBI v2.0 Classification	Instrument Selection Criteria Not Met
Language Sample Analysis	Supplemental	Well-established, broadly applicable to the intended population (e.g., adult and/or pediatric), and generally accepted by the scientific community? Broadly validated with demonstrated utility? Reliable? Low burden to participants and investigators?
Military Acute Concussion Evaluation (MACE) Military Acute Concussion Evaluation (MACE 2)	Supplemental	Broadly validated with demonstrated utility? Reliable? Low burden to participants and investigators? Crosscutting relevance for population groups as well as diseases and conditions? International harmonization (International applicability)?
National Institutes of Health (NIH) Toolbox	Supplemental	Clearly Defined? Specific? Low burden to participants and investigators? International harmonization (International applicability)?
Peabody Developmental Motor Scales 2nd-Edition (PDMS-2) Peabody Developmental Motor Scales 3rd-Edition (PDMS-3)	Supplemental	Broadly validated with demonstrated utility? Low burden to participants and investigators? International harmonization (International applicability)?
Percentage of Consonants Correct-Revised (PCC-R)	Supplemental	Well-established, broadly applicable to the intended population (e.g., adult and/or pediatric), and generally accepted by the scientific community? Broadly validated with demonstrated utility? Reliable? Standard measurement protocols exist? Low burden to participants and investigators?
Tasks of Executive Control (TEC)	Supplemental	Reliable? Standard measurement protocols exist? Low burden to participants and investigators? Crosscutting relevance for population groups as well as diseases and conditions? Rural vs. Urban (Feasibility of Acquisition)? International harmonization (International applicability)?
Verbal Motor Production Assessment for Children (VMPAC)	Supplemental	Well-established, broadly applicable to the intended population (e.g., adult and/or pediatric), and generally accepted by the scientific community? Broadly validated with demonstrated utility?



Instrument Name	TBI v2.0 Classification	Instrument Selection Criteria Not Met
Verbal Motor Production Assessment for Children, Revised Edition (VMPAC-R)		Reliable? Crosscutting relevance for population groups as well as diseases and conditions? International harmonization (International applicability)?

Instruments for Future Consideration

- Berg Balance Scale
- Timed Up and Go
- Sensory Organization Test (SOT)
- Functional Reach Test Forward
- Gait Speed (4m, 6m, 10m or 25 foot walk)

NINDS CDE Notice of Copyright Bedside Western Aphasia Battery-Revised

Availability	Please visit this website for more information about the instrument: Bedside Western Aphasia Battery-Revised
Classification TBI v3.0 Classification Pending	Supplemental: Traumatic Brain Injury (TBI)
Short Description of Instrument	<p>The Bedside Western Aphasia Battery-Revised (Bedside Record Form), a shortened version of the Western Aphasia Battery-Revised (WAB-R), is designed to evaluate a participant's language function following stroke, dementia, or other acquired neurological disorder (Kertesz, 2006).</p> <p>The Bedside Record Form provides quick assessment for clinicians with time constraints and busy schedules, or patients that cannot tolerate a longer assessment. The Bedside Record Form measures linguistics skills to assess for the presence of aphasia and certain nonlinguistic skills, such as drawing, calculation, block design, and praxis. The results provide diagnostic information as to the types of aphasia the participant may have.</p>
Comments/Special Instructions	
Scoring and Psychometric Properties	<p>Scoring: The WAB-R uses a criterion cut score norm. Available scores for the Bedside Record Form include Beside Aphasia Score, Bedside Language Score, and Bedside Aphasia Classification (Pearson Education Inc., 2020).</p> <p>Psychometric Properties: See Kertesz, 2006 for psychometric properties information.</p>
Rationale/Justification	<p>Strengths:</p> <p>Weaknesses:</p>
References	<p>Key References: Kertesz, A. (2006). Western aphasia battery revised. San Antonio, TX: Harcourt Assessment. Retrieved 10May2024: https://www.pearsonassessments.com/store/usassessments/en/Store/Professional-Assessments/Speech-%26-Language/Western-Aphasia-Battery-Revised/p/100000194.html</p> <p>Pearson Education, Inc. WAB™-R Brochure. (2020). Retrieved 27Oct2021: https://www.pearsonassessments.com/content/dam/school/global/clinical/us/assets/wab-r/wabr-brochure.pdf</p> <p>Additional Reference(s): Kertesz A. The Western Aphasia Battery: a systematic review of research and clinical applications. Aphasiology. 2022;36(1):21-50.</p> <p>TBI-Specific Reference(s):</p> <p><i>Document last updated October 2024 December 2025</i></p>

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Beery-Buktenica Developmental Test of Visual-Motor Integration (Beery VMI)

Availability	Please visit this website for more information about this instrument: Beery-Buktenica Developmental of Visual Motor Integration Sixth Edition
Classification TBI v3.0 Classification Pending	<p>Supplemental: Cerebral Palsy (CP), Mitochondrial Disease (Mito), Multiple Sclerosis (MS), Neuromuscular Diseases (NMD), and Spinal Muscular Atrophy (SMA); and Traumatic Brain Injury (TBI)</p> <p>Exploratory: Sport-Related Concussion (SRC)</p>
Short Description of Instrument	<p>Developed in 2010, the Beery-Buktenica Developmental Test of Visual-Motor Integration (Beery VMI) helps assess the extent to which individuals can integrate their visual and motor abilities. The test presents the examinee with drawings of 30 geometric forms, arranged in developmental sequence from less to more complex. The examinee simply copies these forms in the Test Booklet. A Short Form, composed of 21 drawings, is often used with children ages 2 to 7 years. Supplemental tests of Visual Perception and Motor Coordination are available.</p> <p>The Beery VMI can be used by psychologists, learning disability specialists, school counselors, teachers, and other professionals to:</p> <ul style="list-style-type: none"> • Identify individuals who may have difficulty with visual-motor integration • Make appropriate referrals for needed services • Test the effectiveness of educational and other interventions • Evaluate neuropsychological problems in older adults • Inform diagnoses of dementia or Alzheimer's <p>The Beery VMI has been used in numerous studies of cerebral palsy, including comparative studies with typically developing peers, studies of brain behavior relationships, and intervention outcome studies.</p>
Comments/Special Instructions	<p>Ages: 2-18 y</p> <p>Administration: paper-pencil</p> <p>Administration Time: 10-15 minutes</p> <p>Scoring: Manual</p> <p>Accessibility: CP MACS I-II</p> <p>Norms: Normative sample was 1,737 individuals aged 2 to 18 years (2010) and 1,021 adults aged 19-100 (2006). In sixth edition updated norms for ages 2 through 18; Adult norms are included for ages 19 and above but were not updated in this edition.</p>

Scoring and Psychometric Properties	Scoring: One point is awarded for each correct imitated or copied item. A ceiling score is established after 3 consecutive forms have not been passed and the standardized score has a mean of 100 and a standard deviation of 15.		
	Standard Score Interpretation (Beery & Beery 2010)		
	Standard Score	Performance	% of age groups
	129	Very high	2
	120 – 129	High	7
	110 – 119	Above average	16
	90 – 109	Average	50
	80 – 89	Below average	16
	70 – 79	Low	7
	< 70	Very low	2
	Psychometric Properties: According to Howe (2013) test/retest reliability (ICC = .89), interrater/intrarater reliability (ICC = .92) is excellent elementary aged children in handwriting. For preschool aged children Simmons & Probst (2009) showed that test/retest reliability was adequate. Interrater/intrarater reliability (ICC = .93) for kindergarten, first grade and second grade students is excellent (Pfeifer, 2015).		
Rationale/Justification	Strengths: The test is suitable for children, adolescents, adults, and seniors aged 2-100 years. The test is an economical and convenient screen for visual-motor deficits that can lead to learning, behavior and neuropsychological problems.		
	Weaknesses: The Beery VMI was not developed or intended to be used to assess handwriting ability. (Pfeiffer, 2015). As such it should be used with caution as a tool to assess handwriting in children. There are also limitations of using the Beery VMI when determining the effectiveness of interventions (Howe, 2013).		
	Sport-Related Concussion Specific:		
	Strengths: The Beery VMI is used in other medical disorders that affect neurologic function.		
	Weaknesses: The scale is not widely used in concussion studies and though it may be part of an overall neuropsychological evaluation, it is unlikely to be a short stand-alone measure.		
References	Key References: Beery KE & Beery NA. The Beery-Buktenica Developmental Test of Visual-Motor Integration Sixth		

Edition [Internet]. [cited 03 Aug 2023] Available from:
<https://www.pearsonassessments.com/store/usassessments/en/Store/Professional-Assessments/Academic-Learning/Brief/Beery-Buktenica-Developmental-Test-of-Visual-Motor-Integration-%7C-Sixth-Edition/p/100000663.html>

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Skranes J, Evensen KI, Løhaugen GC, Martinussen M, Kulseng S, Myhr G, Vik T, Brubakk AM. Abnormal cerebral MRI findings and neuroimpairments in very low birth weight (VLBW) adolescents. Eur J Paediatr Neurol. 2008 Jul;12(4):273-83.

TBI-Specific Reference(s):

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Brief Visuospatial Memory Test Revised (BVMT-R)

Availability	Please visit this website for more information about the instrument: Brief Visuospatial Memory Test – Revised
Classification TBI v3.0 Classification Pending	<p>NeuroRehab Supplemental – Highly Recommended</p> <p>Recommendations for Use: Indicated for studies requiring a measure of visual memory.</p> <p>Supplemental: Cerebral Palsy (CP), Epilepsy, Mitochondrial Disease (Mito), Multiple Sclerosis (MS), Sport-Related Concussion (SRC), and Stroke, and Traumatic Brain Injury (TBI)</p>
Short Description of Instrument	<p>Author: Ralph H. B. Benedict, PhD</p> <p>The Brief Visuospatial Memory Test – Revised (BVMT-R) can be used as part of a neuropsychological battery, as a screening measure, and as a repeatable measure to document changes over time. Designed to be easily administered in clinical settings or at the bedside, the test can assess participants for visuospatial memory issues related to head trauma, psychiatric disorder, adult learning disability and mixed diagnoses such as stroke and vascular dementia.</p> <p>The BVMT-R can be administered in 10-15 minutes (plus a 25-minute delay between learning and delayed recall trials and scored in 10-15 minutes by an experienced examiner.</p> <p>Purpose: Measure of visuospatial memory</p> <p>Age Range: 18 to 79 years</p> <p>Administration: Individual</p> <p>Administration Time: 10-15 minutes (plus a 25-minute delay between learning and delayed recall trials)</p> <p>Scoring Time: 10-15 minutes by experienced examiner</p>
Comments/Special Instructions	<p>The BVMT-R is designed for easy administration in clinical settings or at the bedside.</p> <p>Six equivalent, alternate stimulus forms consisting of six geometric figures printed in a 2 x 3 array on separate pages.</p> <p>In three Learning Trials, the participant views the stimulus page for 10 seconds and is asked to draw as many of the figures as possible in their correct location on a page in the response booklet. A Delayed Recall Trial is administered after a 25-minute delay. Lastly, a Recognition Trial, in which the participant is asked to identify which of 12 figures were included among the original geometric figures, is administered.</p> <p>An optional Copy Trial may be administered to screen for severe visuoconstruction deficits and to help in scoring recall responses.</p>
Scoring and Psychometric Properties	<p>Scoring: Twelve scores may be derived from BVMT-R performance. Recall performance is recorded for each of the immediate recall trials (Trial 1, Trial 2, and Trial 3) and for the delayed recall trial (Delayed Recall).</p> <p>The recall scores are combined to make three additional summary</p>

	<p>measures of learning and memory.</p> <p>Recognition Hits and False Alarms are recorded during the delayed recognition task. Recognition Hits are calculated as the number of correct “yes” responses to target items, and Recognition False Alarms are calculated as the number of incorrect “yes” responses to nontarget items.</p> <p>Psychometric Properties: Reliability coefficients range from .96 to .97 for the three Learning Trials, .97 for Total Recall, and .97 for Delayed Recall. Test-retest reliability coefficients range from .60 for Trial 1 to .84 for Trial 3. The BVMT-R correlates most strongly with other tests of visual memory and less strongly with tests of verbal memory.</p>
Rationale/Justification	<p>Strengths: The BVMT-R is briefer than most other visual memory measures. It offers six equivalent alternative forms, which makes it more clinically useful for serial evaluations. It also includes a 3-trial learning phase, allowing for examination of visual learning slope which more closely parallels common list learning verbal memory tests.</p> <p>Weaknesses: Although classified as a visual memory measure, stimuli may be verbally encoded. Scores on the delayed recognition trial are limited in their distribution range, with many participants scoring at ceiling levels. The BVMT-R requires upper extremity function sufficient for drawing simple shapes.</p>
References	<p>Key Reference(s): Benedict RHB, Schretlen D, Groninger L, Dobraski M, Shpritz B. Revision of the brief visuospatial memory test: Studies of normal performance, reliability, and validity. Psychol Assess. 1996;8(2):145-53.</p> <p>Additional References: Bailey KC, Soble JR, Bain KM, Fullen C. Embedded Performance Validity Tests in the Hopkins Verbal Learning Test-Revised and the Brief Visuospatial Memory Test-Revised: A Replication Study. Arch Clin Neuropsychol. 2018 Nov 1;33(7):895-900.</p> <p>Benedict RH, Groninger L. Preliminary standardization of a new visuospatial memory test with six alternate forms. Clin Neuropsychol 1995 Feb; 9(1):11-6.</p> <p>Campanholo KR, Conforto AB, Rimkus CM, Miotto EC. Cognitive and Functional Impairment in Stroke Survivors with Basilar Artery Occlusive Disease. Behav Neurol. 2015;2015:971514.</p> <p>Díaz-Santos M, Suárez PA, Marquine MJ, Umlauf A, Rivera Mindt M, Artiola I Fortuny L, Heaton RK, Cherner M. Updated demographically adjusted norms for the Brief Visuospatial Memory Test-revised and Hopkins Verbal Learning Test-revised in Spanish-speakers from the U.S.-Mexico border region: The NP-NUMBRS project. Clin Neuropsychol. 2021 Feb;35(2):374-95.</p> <p>Duff K. Demographically corrected normative data for the Hopkins Verbal Learning Test-Revised and Brief Visuospatial Memory</p>

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TBI-Specific Reference(s):

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Comprehensive Assessment of Spoken Language, Second Edition (CASL-2)

Availability	Please visit this website for more information about the instrument: Comprehensive Assessment of Spoken Language, Second Edition
Classification TBI v3.0 Classification Pending	Supplemental: Mitochondrial Disease (Mito)
Short Description of Instrument	<p>CASL-2 is an in-depth evaluation of an individual's oral language skills in children and young adults aged 3 to 21. The battery consists of 14 subtests, that each measure a specific oral language skill. A verbal or non- verbal response is required; however, reading or writing ability is not needed to complete this measure.</p> <p>Measures language knowledge – form and content with four categories:</p> <ol style="list-style-type: none"> 1. Lexical/Semantic 2. Syntactic 3. Supralinguistic 4. Pragmatic <p>Measures language performance – systems used to process language with a focus on two systems:</p> <ol style="list-style-type: none"> 1. Auditory comprehension 2. Oral expression <p>Administration time includes 5-10 minutes for each subtest, 30-45 minutes for children aged 3-6 years and 45-60 minutes for individuals aged 7-21 years.</p>
Comments/Special Instructions	Refer to articles on CASL-2 in individuals with Autism Spectrum Disorder.
Scoring and Psychometric Properties	<p>Scoring:</p> <ul style="list-style-type: none"> • Standard scores for index level and subtest level <p><u>Indices:</u></p> <ul style="list-style-type: none"> • General Language Ability Index • Receptive Language Index • Expressive Language Index • Lexical/Semantic Index – receptive vocabulary, antonyms, synonyms, expressive vocabulary, idiomatic language • Syntactic Index – sentence expression, grammatical morphemes, sentence comprehension, grammaticality judgment • Supralinguistic Index – nonliteral language, meaning from context, inference, double meaning, pragmatic language <p>Psychometric Properties:</p> <ul style="list-style-type: none"> • Normative sample of 2,394 nationally representative children and young adults aged 3 to 21 years, 11 months • Clinical sample collected with 271 individuals who had a clinical diagnosis of expressive and/or receptive language disorder, hearing impairment, autism spectrum disorder,

	<p>social (pragmatic) communication disorder, intellectual disability, learning disability, and developmental delay</p> <ul style="list-style-type: none"> • Strong internal consistency, test-retest reliability and interrater reliability • Supportive evidence of validity
Rationale/Justification	<p>Strengths:</p> <ul style="list-style-type: none"> • Alternative scoring guidelines for nonstandard English dialects available • Assesses many aspects of spoken language <p>Weaknesses:</p>
References	<p>Key References:</p> <p>Carrow-Woolfolk E. Comprehensive Assessment of Spoken Language, Second Edition (CASL-2) [Manual]. Torrance, CA: Western Psychological Services; 2017.</p> <p>Carrow-Woolfolk E. Comprehensive Assessment of Spoken Language, (CASL) [Manual]. Torrance, CA: Western Psychological Services; 1999.</p> <p>Additional References:</p> <p>Hoffman LM, Loeb DF, Brandel J, Gillam RB. Concurrent and construct validity of oral language measures with school-age children with specific language impairment. J Speech Lang Hear Res. 2011 Dec;54(6):1597-608.</p> <p>Knight D. (2011). Comprehensive Assessment of Spoken Language. In: Encyclopedia of Child Behavior and Development. (Goldstein S & Naglieri JA, Eds.). Boston, MA. Springer.</p> <p>TBI-Specific Reference(s):</p> <p><i>Document last updated March 2024 January 2026</i></p>

NINDS CDE Notice of Copyright

Controlled Oral Word Association Test (COWAT) Subtest of the Multilingual Aphasia Examination (MAE)

Availability	Please visit this website for more information about the instrument: Controlled Oral Word Association Test
Classification TBI v3.0 Classification Pending	<p>NeuroRehab Supplemental – Highly Recommended</p> <p>Recommendations for Use: Indicated for studies requiring a measure for language or executive functions (i.e., taps into prefrontal language circuits).</p> <p>Supplemental – Highly Recommended: Epilepsy and Sport-Related Concussion (SRC)</p> <p>Supplemental: Mitochondrial Disease (Mito), Multiple Sclerosis (MS), and Stroke, and Traumatic Brain Injury (TBI)</p>
Short Description of Instrument	<p>The Controlled Oral Word Association Test (COWAT) is a measure of verbal fluency and is a subtest of the Multilingual Aphasia Examination (Benton, Hamsher, & Sivan, 1994).</p> <p>The COWAT uses the three letter set of F, A, and S (alternative: C, F, and L) to assess phonemic fluency. Individuals are given 1 min to name as many words as possible beginning with one of the letters. The procedure is then repeated for the remaining two letters (see Strauss et al., 2006 and Benton et al., 1994 for specific administration instructions).</p>
Comments/Special Instructions	
Scoring and Psychometric Properties	<p>Scoring: The data collection form provides numbered lines on which the participant's responses can be recorded. If the participant's speed of word production is too fast to permit verbatim recording, a "+" should be recorded to indicate a correct response. Total all correct answers.</p> <p>Psychometric Properties: The reliability and validity of two qualitative scoring systems for the COWAT (Benton et al., 1983a,b) were examined in 108 healthy young adults. The scoring systems developed by Troyer et al., 1997 and Abwender et al., 2001 each demonstrated excellent interrater reliability (all indices at or above $r_{icc} = .9$). Consistent with previous research (Ross, 2003), test-retest reliability coefficients ($N = 53$; M interval 44.6 days) for the qualitative scores were modest to poor ($r_{icc} = .6$ to $.4$ range).</p>
Rationale/Justification	<p>Strengths: The COWAT has a rich history of use in mild TBI and sport-related concussion, particularly for older adolescents and adults, as well as many other adult disorders of the CNS (e.g., age-related neurodegenerative disease, epilepsy, MS, HIV, Huntington's disease, etc.). Quick to administer. Appears sensitive to TBI and predicts severity. Strong psychometric properties with representative normative standards available (Heaton et al., 2004; Mayo's Older Americans Normative Study – Steinberg et al., 2005). There is some neuroanatomical specificity to left prefrontal speech areas, namely the left inferior frontal gyrus (Baldo et al., 2006; Grogan et al., 2009; Melrose et al., 2009), though other</p>

	<p>nonspecific cognitive skills/brain regions also play a role in performance. It can be compared to animal fluency performance.</p> <p>Weaknesses: Less use with children. The abilities underlying performance on the test can be varied (generativity, working memory, processing speed). Highly influenced by premorbid verbal IQ.</p>
References	<p>Key References:</p> <p>Benton AL. Development of a multilingual aphasia battery. Progress and problems. J Neurol Sci. 1969 Jul-Aug;9(1):39-48.</p> <p>Benton AI, Hamsher K. Multilingual Aphasia Examination. Iowa City, University of Iowa Hospitals, 1978.</p> <p>Benton AI, Hamsher K. Multilingual Aphasia Examination. Iowa City, Department of Neurology, University of Iowa Hospitals and Clinics., 1983a.</p> <p>Benton AI, Hamsher K. Multilingual Aphasia Examination. Iowa City: AJA Associates; 1989</p> <p>Benton AL, Hamsher KD, Sivan AB. Multilingual Aphasia Examination. Lutz, FL: Psychological Assessment Resources, Inc., 1994.</p> <p>Additional References:</p> <p>Abwender DA, Swan JG, Bowerman JT, Connolly SW. Qualitative analysis of verbal fluency output: review and comparison of several scoring methods. Assessment. 2001 Sep;8(3):323-38.</p> <p>Baldo JV, Schwartz S, Wilkins D, Dronkers NF. Role of frontal versus temporal cortex in verbal fluency as revealed by voxel-based lesion symptom mapping. J Int Neuropsychol Soc. 2006 Nov;12(6):896-900.</p> <p>Benton AL, Hamsher K, Varney NR, Spreen O. Contributions to Neuropsychological Assessment. New York: Oxford University Press, 1983b.</p> <p>Chahal N, Barker-Collo S, Feigin V. Cognitive and functional outcomes of 5-year subarachnoid haemorrhage survivors: comparison to matched healthy controls. Neuroepidemiology. 2011;37(1):31-8.</p> <p>Filley CM, Brown MS, Onderko K, Ray M, Bennett RE, Berry-Kravis E, Grigsby J. White matter disease and cognitive impairment in FMR1 premutation carriers. Neurology. 2015 May 26;84(21):2146-52.</p> <p>Gómez Beldarrain M, García-Moncó JC, Quintana JM, Llorens V, Rodeño E. Diaschisis and neuropsychological performance after cerebellar stroke. Eur Neurol. 1997;37(2):82-9.</p> <p>Grogan A, Green DW, Ali N, Crinion JT, Price CJ. Structural correlates of semantic and phonemic fluency ability in first and second languages. Cereb Cortex. 2009 Nov;19(11):2690-8.</p>

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TBI-Specific Reference(s):

Document last updated ~~March 2024~~ January 2026

NINDS CDE Notice of Copyright

Functional Gait Assessment

(New for TBI)

Availability	Please visit this website for more information about the instrument: <u>Functional Gait Assessment</u>
Classification TBI v3.0 Classification Pending	<p>NeuroRehab Supplemental – Highly Recommended: Recommendations for Use: Indicated for studies requiring a measure of motor function. Recommended for Sport-Related Concussion (SRC) studies.</p> <p>Supplemental-Highly Recommended: Sport-Related Concussion (SRC) Persistent/Chronic (3 months and greater post concussion)</p> <p>Supplemental: Sport-Related Concussion (SRC) Subacute (after 72 hours to 3 months)</p> <p>Exploratory: Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage (SAH)</p>
Short Description of Instrument	<p>The Functional Gait Assessment is used to evaluate postural stability during various walking exercises. It is a modification of the Dynamic Gait Index and was developed to improve reliability and decrease the ceiling effect.</p> <p>Normal, fast, slow walking with vertical and horizontal turning of the head; backward walking; stair ascension/descension</p> <p>Walking with eyes closed, walking over obstacles, tandem walking</p> <p>Avoids ceiling effects of Berg Balance and Dynamic Gait Index</p> <p>Cut Score 22/30 to classify falls risk.</p>
Comments/Special Instructions	<p>Requirements: A marked 6-m (20-ft) walkway that is marked with a 30.48-cm (12-in) width</p> <p>It is a 10-item test and can be performed with or without an assistive device.</p> <p>Time to administer: 5-10 minutes</p> <p>Administration mode: paper/pen</p>
Scoring and Psychometric Properties	<p>Scoring: Each item is scored on a 4-level ordinal scale from 0 - 3, with lower scores indicating greater overall impairment:</p> <p>0 = severe impairment</p> <p>1 = moderate impairment</p> <p>2 = mild impairment</p> <p>3 = normal ambulation</p> <p>Psychometric Properties:</p>
Rationale/Justification	<p>Strengths:</p> <p>Weaknesses:</p>

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NINDS CDE Notice of Copyright Functional Independence Measure (FIM)

Availability	<p>Please visit this website for more information about the instrument: Functional Independence Measure</p> <p>The FIM is proprietary. For further information about obtaining the scale, syllabus, and training materials please contact:</p> <ul style="list-style-type: none"> • Uniform Data System for Medical Rehabilitation • 270 Northpointe Parkway, Suite 300 • Amherst, New York 14228 • (716) 817-7800 FAX (716) 568-0037 • info@udsmr.org
Classification TBI v3.0 Classification Pending	<p>NeuroRehab Supplemental – Highly Recommended</p> <p>Recommendations for Use: Indicated for studies requiring a measure of Activities of Daily Living.</p> <p>Supplemental: Chiari I Malformation (CM), Multiple Sclerosis (MS), and Stroke, and Traumatic Brain Injury (TBI)</p> <p>Exploratory: Cerebral Palsy (CP), Friedreich’s Ataxia (FA), and Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage (SAH)</p>
Short Description of Instrument	<p>Purpose: The FIM measures the capacity for independence in activities of self-care, sphincter control, transfers, locomotion, communication, and cognition.</p> <p>Overview: The FIM emerged from a thorough developmental process overseen by a National Task Force of rehabilitation research. The National Task force reviewed 36 published and unpublished functional assessment scales before agreeing on an instrument. The FIM is an 18-item scale with each item structured in an ordinal scale. It can be used with all diagnoses within a rehabilitation population. It is viewed as most useful for assessment of progress during inpatient rehabilitation.</p> <p>Time: Evaluation time is 20-30 minutes.</p>
Comments/Special Instructions	<p>The FIM may be completed as an observational scale by rehabilitation clinicians or by trained paraprofessionals, or family members. It can be administered by trained interviewers as a self-report or proxy report instrument, in person or by phone.</p> <p>FIM certification is available and required to officially utilize the tool. A detailed manual guides scoring, based on operationally-defined functional abilities. Most appropriate for Severe and Moderate Disability levels of GOSE; ceiling effects limit utility in Good Recovery.</p> <p>Prior to 2020, the FIM was imbedded in the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI). Subsequently, Section GG of the Standardized Patient Assessment Data Elements replaced the FIM for alignment with</p>

	<p>other post-acute care programs. The FIM can no longer be extracted from the IRF-PAI.</p> <p>The alpha FIM is a subset that has been used in the acute patient setting to assess which patients are appropriate for discharge to a rehabilitation setting. The alpha FIM may be worth exploring in Phase III trials that include assessments of appropriateness of different post-discharge destinations.</p> <p>NeuroRehab-Specific: The FIM is a widely used observational/self-report measure using objective criteria for scoring and therapist or patient/family observations. It is most appropriate for inpatient rehabilitation and during the first year or so after discharge. If the administrator is trained, the FIM can be used as a performance-based measure.</p>
Scoring and Psychometric Properties	<p>Scoring: Scores range from 1 (total or >75% assistance) to 7 (complete independence). The total of the 18 items is the participant's patient's total score, which ranges from 18-126. Scores may be used raw or converted to interval scores.</p> <p>Psychometric Properties: Inter-rater reliability was found to be high for the total score and moderate to substantial for items assessing physical disability, except for the item concerned with assessing independence in walking or in wheelchair. The inter-rater agreement of FIM items in the communication and social cognition subsections was only fair (Hamilton et al., 1991). The internal consistency of the FIM assessment scale was found to be high overall and for patients grouped by impairment, but low for the locomotion subscale (Dodds et al., 1993). Minimal clinically important difference relative to physician assessment has been established for total score and motor and cognitive subscores in post-inpatient rehabilitation stroke patients (Beninato et al., 2006).</p>
Rationale/Justification	<p>NeuroRehab-Specific:</p> <p>Strengths: Very strong use in both inpatient rehab and longitudinal follow-up research. Strong psychometrics, reliability, sensitive to change, very extensive literature. FIM scores based on observations by therapists, trained research staff or can be provided by self-report.</p> <p>Weaknesses: Training needs to be purchased, no longer required to be measured in inpatient rehab. Several important ADL activities are not included: medication; sleep; personal care device management, e.g., insulin shots, hearing aids. The FIM may manifest ceiling or floor effects and may not be appropriate for measuring individuals outside their range of assessment.</p> <p>TBI-Specific:</p> <p>Strengths:</p> <p>Weaknesses:</p>
References	<p>Key Reference(s):</p> <p>Granger CV. The emerging science of functional assessment: our tool for outcomes analysis. Arch Phys Med Rehabil. 1998 Mar;79(3):235-40.</p>

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TBI-Specific Reference(s):

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Functional Independence Measure (FIM) - Motor Subscale

Availability	<p>Please visit this website for more information about the instrument: Functional Independence Measure</p> <p>The FIM is proprietary. For further information about obtaining the scale, syllabus, and training materials please contact: Uniform Data System for Medical Rehabilitation 270 Northpointe Parkway, Suite 300 Amherst, New York 14228 (716) 817-7800 FAX (716) 568-0037 email: info@udsmr.org</p>
Classification TBI v3.0 Classification Pending	<p>Basic: Acute/Hospitalized and Moderate/Severe Rehabilitation Traumatic Brain Injury (TBI)</p> <p>Supplemental: Concussion/Mild TBI and Epidemiology TBI</p>
Short Description of Instrument	<p>The FIM is an 18-item ordinal scale, used with all diagnoses within a rehabilitation population. Items are grouped into two subscales: Motor and Cognitive. The FIM measures degree of independence in activities of self-care, sphincter control, transfers, locomotion, communication, and cognition.</p> <p>FIM was originally an acronym for "Functional Independence Measure". It is still often cited as this in the literature. The current owners of the FIM instrument have decided that the acronym FIM no longer stands for anything and should be referred to only as FIM.</p> <p>The Motor Subscale consists of:</p> <ul style="list-style-type: none"> • Eating • Grooming • Bathing • Dressing, upper body • Dressing, lower body • Toileting • Bladder management • Bowel management • Transfers - bed/chair/wheelchair • Transfers - toilet • Transfers - bath/shower • Walk/wheelchair • Stairs
Comments/Special Instructions	<p>May be completed by rehabilitation clinicians as an observational scale, or by trained paraprofessionals or family members. May be administered by trained interviewers as a self-report or proxy report instrument, in person or by phone. FIM(TM) certification is available and required to officially utilize the tool. A detailed manual guides scoring, based on operationally-defined functional abilities. Administration time is 10-20 minutes.</p> <p>Most appropriate for Severe and Moderate Disability levels of GOSE; ceiling effects limit utility in Good Recovery.</p>

Scoring and Psychometric Properties	<p>Scoring: Each item is scored on a 7 point ordinal scale, ranging from a score of 1 (total or >75% assistance) to a score of 7 (complete independence).</p> <p>The higher the score, the more independent the patient is in performing the task associated with that item.</p> <ol style="list-style-type: none"> 1. Total assistance with helper 2. Maximal assistance with helper 3. Moderate assistance with helper 4. Minimal assistance with helper 5. Supervision or setup with helper 6. Modified independence with no helper 7. Complete independence with no helper <p>The total score for the FIM motor subscale (the sum of the individual motor subscale items) will be a value between 13 and 91.</p> <p>Scores may be used raw or converted to interval scores. Higher scores indicate greater independence.</p> <p>Psychometric Properties:</p>
Rationale/Justification	<p>Strengths:</p> <p>Weaknesses:</p>
References	<p>Key References:</p> <p>Keith RA, Granger CV, Hamilton BB, Sherwin FS. The functional independence measure: a new tool for rehabilitation. Adv Clin Rehabil. 1987;1:6-18.</p> <p>Uniform Data System for Medical Rehabilitation. 2009. The FIM System® Clinical Guide, Version 5.2. Buffalo: UDSMR.</p> <p>Additional References:</p> <p>Granger CV. The emerging science of functional assessment: our tool for outcomes analysis. Arch Phys Med Rehabil. 1998 Mar;79(3):235-240.</p> <p>Wright, J. (2000). The FIM(TM). The Center for Outcome Measurement in Brain Injury. Retrieved 31Dec2025, from: http://www.tbims.org/combi/FIM.</p> <p>TBI-Specific Reference(s):</p> <p>Document last updated June 2019 January 2026</p>

NINDS CDE Notice of Copyright Grooved Pegboard Test

Availability	Please visit this website for more information about the instrument: Grooved Pegboard Test
Classification TBI v3.0 Classification Pending	<p>NeuroRehab Supplemental – Highly Recommended Recommended for general use in disorders affecting the Central Nervous System (CNS). However, its results should be interpreted with care (or in some cases the test should not be used at all) with patients who have significant peripheral injuries affecting hand or finger movement, or long fingernails that affect ability to manipulate small objects, or severe visual disturbance that may invalidate the test for measuring CNS effects. In general, it is indicated for studies requiring a measure for eye-hand motor coordination.</p> <p>It is not recommended for particular use in specific NINDS CDE Disorder(s) but rather is broadly applicable across many CNS disorders.</p> <p>Supplemental: Epilepsy, Mitochondrial Disease (Mito), Multiple Sclerosis (MS), and Stroke, and Traumatic Brain Injury (TBI)</p> <p>Exploratory: Sport-Related Concussion (SRC) and Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage (SAH)</p>
Short Description of Instrument	<p>The Grooved Pegboard Test is a neuropsychological tool that measures fine motor skills, visual-motor coordination and dexterity.</p> <p>Construct measured: Finger and manual dexterity, perceptual-motor speed</p> <p>-</p> <p>Generic vs. disease-specific: Generic</p> <p>-</p> <p>Intended respondent: Patients 20-85 years old</p> <p># of items: 25 pegs</p> <p>-</p> <p># of subscales and names of sub-scales: N/A</p> <p>-</p> <p># of items per sub-scale: N/A</p>
Comments/Special Instructions	Background: The Grooved Pegboard Test is a manipulative dexterity test. This unit consists of 25 holes with randomly positioned slots. Pegs, which have a key along one side, must be rotated to match the hole before they can be inserted. This test requires more complex visual-motor coordination than most pegboards.
Scoring and Psychometric Properties	Scoring: For the right hand trial, the examiner demonstrates that the pegs are placed from participant's left to right, and from right to left for the left hand trial. The dominant hand trial is administered first, followed by the nondominant hand trial. Only one peg is to be picked up at a time, and the participant should immediately be told if more than one is picked up. Also, only one hand is to be used. If necessary, the board should be held steady

	<p>for the participant. In the case of severe motor impairment, the participant should attempt the task just to see if any of the pegs can be put in. Any factor that may affect the participant's performance should be noted, e.g., sore finger, bandage, etc.</p> <p>Record, in seconds, the length of time required to perform each trial beginning when the participant starts the task until the last peg is put in, or the test is discontinued. A trial may be discontinued after five minutes. In such cases, the difficulty is described, and the scores are given "A" flags, indicating an incomplete test. The second score is the number of "drops" made during each trial. A "drop" is any unintentional drop of a peg from the time the participant attempts to pick up the peg from the tray until it is placed correctly in the hole. If one peg is turned with the hand not being evaluated, this is noted. If, however, this occurs more than once, the score is given a "D" flag for a nonstandard assessment. The third score is the number of pegs correctly placed in the holes for each trial. The score for each trial is the total time (in seconds) to correctly place the 25 pegs; if the participant is unable to complete the test in the allotted time, the score may be prorated.</p> <p>The examiner encourages the participant to perform the task as quickly as possible, telling him or her to speed up if necessary. The pegs must be inserted in the board in the exact order and in the correct direction. The task is performed once with the dominant and then once with the non-dominant hand.</p> <p>Psychometric Properties: The Grooved Pegboard Test had good test-retest reliability for both hands (0.91 and 0.85 for right and left hands, respectively). The Grooved Pegboard Test correlated with BOT at -0.50 to -0.63 and with Purdue Pegboard at -0.73 to -0.78.</p>
Rationale/Justification	<p>Strengths: Quick to administer, good normative standards, appropriate for use across a broad range of CNS disorders.</p> <p>Weaknesses: Requires the purchase of the pegboard and metal pegs (Lafayette Instrument Company, or Psychological Assessment Resources, Inc.) and may not be valid in patients with peripheral injuries to the upper extremities or significant visual disturbance. The Grooved Pegboard Test requires longer administration time than some other measures and is challenging for the youngest children and oldest adults.</p> <p>Administration: Each trial typically takes 60-70 seconds; a trial may be discontinued if it takes more than 5 minutes.</p> <p>TBI Rationale: The GPT is a widely used test of fine motor skill that has proven sensitive to the effects of TBI and many other CNS disorders.</p> <p>Epilepsy Rationale: Motor speed may be assessed by a variety of procedures, including measures of reaction time (Thompson & Trimble, 1983) or more conventional measures of motor speed used in clinical neuropsychological evaluations (Grooved Pegboard, Finger Tapping). While reaction time measures are</p>

	<p>perhaps extremely pure motor speed measures and have been used in epilepsy research (Thompson & Trimble, 1983), they are not widely used clinically and have limited normative data. More conventional clinical measures have the advantage of familiarity and strong normative databases and are brief and direct in administration time and directions.</p> <p>The Grooved Pegboard Test was selected due to its widespread use and its purported greater sensitivity to lateralized brain impairment than other motor speed measures such as finger tapping. Importantly, one of the reasons that finger tapping was not selected is that it has historically been given with various sets of instructions and the timing of each 10 second trial introduces significant measurement error. The Grooved Pegboard Test has been effectively used to characterize fine motor speed in multiple epilepsy studies.</p> <p>Subarachnoid Hemorrhage (SAH) Rationale: The GPT has been used in various SAH studies, including large scale prospective trials, such as the IHAST, and institutional databases, such as from the Columbia group. It is well-normed and reference values are available for the age range of SAH patients. For these reasons, the Swiss national standard of neuropsychological assessment after SAH includes the GPT.</p> <p>NeuroRehab Rationale: Supplemental – Highly Recommended measure because it has perceptual-motor, sustained attention/effort, and processing speed components.</p>
References	<p>Key Reference: Matthews CG, Klove H. Instruction manual for the adult neuropsychology test battery. Madison, WI: University of Wisconsin Medical School; 1964.</p> <p>Additional References: Heaton A, Gooding A, Cherner M, Umlauf A, Franklin DR, Rivera Mindt M, Suárez P, Artiola I Fortuni L, Heaton RK, Marquine MJ. Demographically-adjusted norms for the Grooved Pegboard and Finger Tapping tests in Spanish-speaking adults: Results from the Neuropsychological Norms for the U.S.-Mexico Border Region in Spanish (NP-NUMBRS) Project. Clin Neuropsychol. 2021 Feb;35(2):396-418.</p> <p>Heaton RK, Miller SW, Taylor MJ, Grant I. Revised Comprehensive Norms for an Expanded Halstead-Reitan Battery: Demographically Adjusted Neuropsychological Norms for African American and Caucasian Adults Profession Manual. Lutz, FL: Psychological Assessment Resources; 2004</p> <p>Ruff RM, Parker SB. Gender- and age-specific changes in motor speed and eye-hand coordination in adults: normative values for the Finger Tapping and Grooved Pegboard Tests. Percept Mot Skills. 1993 Jun;76(3 Pt 2):1219-30.</p> <p>Stienen MN, Zweifel-Zehnder AE, Chicherio M, Studerus-Germann A, Bläsi S, Rossi S, Gutbrod K, Schmid N, Beaud V, Mondadori C, Brugger P, Sacco L, Müri R, Hildebrandt G, Keller</p>

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TBI-Specific Reference(s):

Document last updated ~~March 2024~~ January 2026

NINDS CDE Notice of Copyright

Gross Motor Function Measure (GMFM-88, GMFM-66)

Availability	Please visit this website for more information about the instrument: Gross Motor Function Measure
Classification TBI v3.0 Classification Pending	<p>Supplemental - Highly Recommended: Cerebral Palsy (CP) Recommendations for use: Indicated for studies measuring gross motor physical function.</p> <p>Supplemental: Traumatic Brain Injury (TBI), Spinal Muscular Atrophy (SMA), Myotonic Dystrophy (DM) and Mitochondrial Disease (Mito)</p> <p>Exploratory: Congenital Muscular Dystrophy (CMD), Duchenne/Becker Muscular Dystrophy (DMD/BMD) and Spinal Cord Injury (SCI)-Pediatric (5 months to 16 years)</p>
Short Description of Instrument	<p>Construct measured: Gross Motor Physical Function</p> <p>-</p> <p>Generic vs. disease specific: Generic</p> <p>-</p> <p>Means of administration: Examiner administered.</p> <p>-</p> <p>Intended respondent: Administrator.</p> <p>The Gross Motor Function Measure (GMFM) is a standardized assessment of physical function and change in physical function in children with cerebral palsy. The GMFM-88 has also been used for assessment of children with Down syndrome and traumatic brain injury. The GMFM-66 (created using Rasch analysis of GMFM-88) has been validated only in children with CP. Both GMFM-88 and GMFM-66 measure gross motor function and change in function over time in 5 domains of Lying & Rolling; Sitting; Crawling & Kneeling; Standing; and Walking, Running & Jumping. The GMFM-66 also provides information on level of difficulty of each item. Both tests are free to use with translations in Spanish and German.</p> <p>Used as an outcome measure in many previous therapeutic trials for children with cerebral palsy: dorsal rhizotomy, intrathecal baclofen, physical therapy, strength training, muscle tendon surgery, gait, and overall fitness. This instrument is also used in trials of children with Down syndrome, traumatic brain injury, musculoskeletal disease, and lysosomal storage disease.</p> <p>Administration Time: Approximately 45-60 minutes. Administration time varies depending on the child's ability, level of cooperation, and skill of the administrator. A training manual, CD and standardized scoring forms are available. The manual contains information on score interpretation and is required for administration and scoring.</p>
Comments/Special Instructions	The GMFM should be administered in an area that permits free movement for ambulatory children (one item requires a 15-foot run in one direction and return). In general, no special tools or equipment are required other than those typically found in a

	<p>pediatric therapy gym. As the GMFM is intended to measure change in function over time, keeping the environment similar at each testing for the child is important for consistency in administration.</p> <p>Updated Manual in 2021: Gross Motor Function Measure (GMFM-66 & GMFM-88) User's Manual 3rd Edition (July 2021). The Gross Motor Ability Estimator (GMAE) app is available for real-time recording of data. Training tape and Criterion test are available for examiners.</p>
Scoring and Psychometric Properties	<p>Scoring: The test is administered by a trained individual. A training manual, CD and standardized scoring forms are available. The manual contains information on score interpretation and is required for administration and scoring.</p> <p>A four-point scoring system is used for each item in the GMFM-88 and GMFM-66 (Range of 0 (Does not initiate) to 3 (Completes)). These are added to obtain raw and percent scores for each of the five dimensions, selected goal areas and for total score. Higher scores indicate higher functional level. The GMFM-88 scores can be summed and used to calculate both raw and percent scores for each of the five dimensions. GMFM-66 must be scored using the Gross Motor Ability Estimator (GMAE).</p> <p>Psychometric Properties: The GMFM 88 is a validated, age-appropriate tool for children with severe neurological and neuromuscular impairment. While currently validated for children with cerebral palsy (5 months to 16 years), the instrument considers quality of movement and is designed to track change over time. The GMFM does not provide age equivalency; all items can be performed by a typically developing 5-year-old. Allows for testing of all motor skills, allowing children to demonstrate strength in any skill area, rather than cutting off due to inability to perform a skill.</p> <p>Cerebral Palsy-specific: This has been validated in children with cerebral palsy ages 5 months to 16 years old. Reliability is high for both GMFM-88 and GMFM 66. A clinically important change in score is dependent on the dimensions being tested, GMFCS level of the child, and which GMFM is being used. Please refer to the GMFM manual for more information.</p>
Rationale/Justification	<p>Strengths: The GMFM 88 is a clinical measure designed to evaluate change in gross motor function in children with cerebral palsy, who have many neuromuscular features also seen in children with mitochondrial diseases.</p> <p>The GMFM 88 total score is the most frequent measure employed to detect changes in gross motor function in interventional trials. Can measure change even in children with little neurological functioning using subtle changes (head turning).</p> <p>Weaknesses: Not yet proven to be reliable or validated for mitochondrial disease. It takes up to 1 hour and training is necessary for use of the GMFM with a training video available.</p>

	<p>SCI-Pediatric-Specific: There are no studies of the GMFM for youth with SCI.</p> <p>Cerebral Palsy-Specific: It is a well-validated, commonly used measure. However, it can take a significant amount of time to administer.</p>
<p>References</p>	<p>Key References:</p> <p>Russell DJ, Avery LM, Rosenbaum PL, Raina PS, Walter SD, Palisano RJ. Improved scaling of the gross motor function measure for children with cerebral palsy: evidence of reliability and validity. <i>Phys Ther.</i> 2000 Sep;80(9):873-85.</p> <p>Russell DJ, Rosenbaum PL, Cadman DT, Gowland C, Hardy S, Jarvis S. The gross motor function measure: a means to evaluate the effects of physical therapy. <i>Dev Med Child Neurol.</i> 1989 Jun;31(3):341-52.</p> <p>Russell DJ, Wright M, Rosenbaum PL, Avery LM (2021). <i>Gross Motor Function Measure (GMFM-66 & GMFM-88) User's Manual</i> (3rd Edition). Mac Keith Press.</p> <p>Additional References:</p> <p>Alotaibi M, Long T, Kennedy E, Bavishi S. The efficacy of GMFM-88 and GMFM-66 to detect changes in gross motor function in children with cerebral palsy (CP): a literature review. <i>Disabil Rehabil.</i> 2014;36(8):617-27.</p> <p>Durkot MJ, De Garavilla L, Caretti D, Francesconi R. The effects of dichloroacetate on lactate accumulation and endurance in an exercising rat model. <i>Int J Sports Med.</i> 1995 Apr;16(3):167-71.</p> <p>Folmes CD, Sowah D, Clanachan AS, Lopaschuk GD. High rates of residual fatty acid oxidation during mild ischemia decrease cardiac work and efficiency. <i>J Mol Cell Cardiol.</i> 2009 Jul;47(1):142-8.</p> <p>Fujii T, Nozaki F, Saito K, Hayashi A, Nishigaki Y, Murayama K, Tanaka M, Koga Y, Hiejima I, Kumada T. Efficacy of pyruvate therapy in patients with mitochondrial disease: a semi-quantitative clinical evaluation study. <i>Mol Genet Metab.</i> 2014 Jun;112(2):133-8.</p> <p>Gandhi M, Finegan BA, Clanachan AS. Role of glucose metabolism in the recovery of postischemic LV mechanical function: effects of insulin and other metabolic modulators. <i>Am J Physiol Heart Circ Physiol.</i> 2008 Jun;294(6):H2576-86.</p> <p>Hanna SE, Bartlett DJ, Rivard LM, Russell DJ. Reference curves for the Gross Motor Function Measure: percentiles for clinical description and tracking over time among children with cerebral palsy. <i>Phys Ther.</i> 2008 May;88(5):596-607.</p> <p>Lundkvist Josenby A, Jarnlo GB, Gummesson C, Nordmark E. Longitudinal construct validity of the GMFM-88 total score and goal total score and the GMFM-66 score in a 5-year follow-up study. <i>Phys Ther.</i> 2009 Apr;89(4):342-50.</p>

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TBI-Specific Reference(s):

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Document last updated ~~December 2024~~ January 2026

NINDS CDE Notice of Copyright High-Level Mobility Assessment Tool (HiMAT) (New for TBI)

Availability	Please visit this website for more information about the instrument: High-Level Mobility Assessment Tool
Classification TBI v3.0 Classification Pending	
Short Description of Instrument	The High-Level Mobility Assessment Tool (HiMAT) was developed to assess high-level mobility in people who have sustained a traumatic brain injury (TBI) (Williams et al., 2004, 2005a, 2006). The 13-item test assesses high-level activities including walking and running, jumping and balance items, stairs, hopping and skipping (Williams et al., 2005a).
Comments/Special Instructions	Originally developed as a unidimensional measure of mobility to minimize the impact of cognitive ability on motor performance, the HiMAT helps to determine when survivors are physically able to return to employment, social, leisure and sporting activities (Williams et al., 2009).
Scoring and Psychometric Properties	Scoring: Each performance (i.e., walking, running, jumping) are converted to a score from 0-4 (or 0-5 in the case of two stair items) for a maximal score of 54 (Williams et al., 2009). Psychometric Properties:
Rationale/Justification	Strengths: Weaknesses:
References	<p>Key References: Williams G, Robertson V, Greenwood K, Goldie P, Morris ME. The high-level mobility assessment tool (HiMAT) for traumatic brain injury. Part 1: Item generation. Brain Inj. 2005a Oct;19(11):925-32.</p> <p>Williams GP, Robertson V, Greenwood KM, Goldie PA, Morris ME. The high-level mobility assessment tool (HiMAT) for traumatic brain injury. Part 2: content validity and discriminability. Brain Inj. 2005b Sep;19(10):833-43.</p> <p>Additional References: Eldridge BJ, Galea MP, Kissane AL, Broder JC, Brilleman SL, Wolfe R, Williams G. High-Level Mobility Assessment Tool Normative Values for Children. Phys Ther. 2020 Feb 7;100(2):324-331.</p> <p>Williams GP, Greenwood KM, Robertson VJ, Goldie PA, Morris ME. High-Level Mobility Assessment Tool (HiMAT): interrater reliability, retest reliability, and internal consistency. Phys Ther. 2006 Mar;86(3):395-400.</p> <p>Williams GP, Rosie J, Denisenko S, Taylor D. Normative Values for the High-Level Mobility Assessment Tool (HiMAT). Intl J Ther Rehabil. 2009 Jul;16(7):370-74.</p> <p>TBI-Specific References: Kleffeldgaard I, Roe C, Sandvik L, Hellstrom T, Soberg HL. Measurement properties of the high-level mobility assessment tool for mild traumatic brain injury. Phys Ther. 2013 Jul;93(7):900-10.</p>

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NINDS CDE Notice of Copyright

Mini-Balance Evaluation Systems Test (Mini-BESTest)

(New for TBI)

Availability	Please visit this website for more information about the instrument: Mini-Balance Evaluation Systems Test
Classification TBI v3.0 Classification Pending	NeuroRehab Supplemental – Highly Recommended Recommendations for Use: Indicated for studies requiring a measure of balance. Exploratory: Spinal Cord Injury (SCI)
Short Description of Instrument	The Mini-Balance Evaluation Systems Test (Mini-BESTest) is a 14-item scale that focuses on dynamic balance. The 14-items belong to four of the six sections found in the original BESTest: “section III ‘Anticipatory Postural Adjustments’ (sit to stand, rise to toes, stand on one leg); section IV ‘Postural Responses’ (stepping in four different directions); section V ‘Sensory Orientation’ (stance - eyes open; foam surface - eyes closed; incline - eyes closed); and section VI ‘Balance during Gait’ (gait during change speed, head turns, pivot turns, obstacles; timed ‘Get Up and Go’ with dual task).” (Franchignoni et al., 2010).
Comments/Special Instructions	
Scoring and Psychometric Properties	Scoring: The Mini-BESTest has a maximum score of 28 points. Each of the 14 items are scored from 0-2: “0” indicates the lowest level of function and “2” the highest level of function. If a participant subject must use an assistive device for an item, that item is scored one category lower. If a participant subject requires physical assistance to perform an item a “0” score is given for that item. Psychometric Properties:
Rationale/Justification	Strengths/Weaknesses: The Mini-BESTest has “shown no ceiling effect, slightly better responsiveness, and could in some neurological populations predict falls” (Jørgensen et al., 2017). The Mini-BESTest has not yet been validated in spinal cord injury (SCI) populations (Jørgensen et al., 2017). NeuroRehab-Specific: This test is newer than the Functional Gait Assessment or Berg Balance Scale (BBS) and has less of a ceiling effect than the BBS so may be better for higher functioning individuals. The downside of the Mini-BESTest is the need for an incline and a block of foam, but the test has good reliability and validity and is used increasingly across populations.
References	Key References: Franchignoni F, Horak F, Godi M, Nardone A, Giordano A. Using psychometric techniques to improve the Balance Evaluation Systems Test: the mini-BESTest. J Rehabil Med. 2010 Apr;42(4):323-31. Franchignoni F, Godi M, Guglielmetti S, Nardone A, Giordano A. Enhancing the usefulness of the Mini-BESTest for measuring dynamic balance: a Rasch validation study. Eur J Phys Rehabil Med. 2015 Aug;51(4):429-37. Additional References: Di Carlo S, Bravini E, Vercelli S, Massazza G, Ferriero G. The Mini-BESTest: a review of psychometric properties. Int J Rehabil Res. 2016 Jun;39(2):97-105.

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SCI-Specific Reference:

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TBI-Specific Reference(s):

Document last updated ~~January 2022~~ January 2026

NINDS CDE Notice of Copyright

Modified Clinical Test of Sensory Interaction on Balance (mCTSIB)

(New for TBI)

Availability	Please visit this website for more information about the instrument: Modified Clinical Test of Sensory Interaction on Balance
Classification TBI v3.0 Classification Pending	
Short Description of Instrument	<p>First described in Shumway-Cook and Horak (1986) the Clinical Test of Sensory Interaction on Balance (CTSIB) evaluates the abilities of individuals to integrate visual, vestibular and somatosensory inputs to maintain balance and provides clinicians with the means to quantify postural control under various conditions (Shirely Ryan AbilityLab, 2013).</p> <p>The Modified CTSIB (mCTSIB) tests for 4 sensory conditions and assesses how well older adults use sensory inputs when one or more sensory systems are compromised (Horn et al., 2015; Müjdecı et al., 2025).</p> <p>The mCTSIB involves individuals standing with their hands at their sides, feet together and performing the following 4 sensory conditions (East, 2025a):</p> <ol style="list-style-type: none"> 1) Stand on firm surface, eyes open 2) Stand on firm surface, eyes closed 3) Stand on foam surface, eyes open 4) Stand on foam surface, eyes closed
Comments/Special Instructions	There is also a pediatric version of the CTSIB (Lotfi et al., 2017; Müjdecı et al., 2025).
Scoring and Psychometric Properties	<p>Scoring: Each test condition is timed for 30 seconds, and the test is terminated (i.e., the timer stops) when the individual opens their eyes, moves their arms, or loses balance. When an individual's arms or feet change position, the test is terminated (Peterka & Loughlin, 2004; Pritt, 2025). If an individual is unable to maintain the position for 30 seconds they are provided with 2 additional attempts. The total times (30s max per condition) are added for a score out of 120s once all conditions are tested. The Sway Index is recorded over the 4 conditions. The higher the sway index, the more unsteady balance an individual has during the test (Dawson et al., 2018).</p> <p>Psychometric Properties: A study by Antoniadou et al. (2020), showed the validity of the mCTSIB test was significantly and positively correlated with the mini-BESTest-GR with $r = -0.652$ and $p < 0.001$.</p>
Rationale/Justification	<p>Strengths:</p> <p>Weaknesses:</p>
References	<p>Key References:</p> <p>Shumway-Cook A, Horak FB. Assessing the influence of sensory interaction of balance. Suggestion from the field. Phys Ther. 1986 Oct;66(10):1548-50.</p> <p>Cohen H, Blatchly CA, Gombash LL. A study of the clinical test of sensory interaction and balance. Phys Ther. 1993 Jun;73(6):346-51; discussion 351-4.</p> <p>East M. (2025a, October 15). Modified Clinical Test of Sensory Interaction on Balance (mCTSIB). Retrieved 07Jan2026, from https://www.interacoustics.com/academy/balance-testing-training/vestibular-rehabilitation/modified-clinical-test-of-sensory-interaction-on-balance-mctsib</p>

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TBI-Specific References:

Document last updated January 2026

NINDS CDE Notice of Copyright NIH Toolbox Motor Battery

Availability	Please visit this website for more information about the instrument: NIH Toolbox Website
Classification TBI v3.0 Classification Pending	Supplemental: Traumatic Brain Injury (TBI) Exploratory: Sport-Related Concussion (SRC) Subacute (after 72 hours to 3 months) and Persistent/Chronic (3 months and greater post concussion)
Short Description of Instrument	Background/Purpose: The National Institutes of Health Toolbox is part of the NIH Blueprint initiative. It seeks to assemble brief, comprehensive assessment tools that will be useful in a variety of settings with a particular emphasis on measuring outcomes in epidemiologic studies and clinical trials across the lifespan. NIH Toolbox Overview: The goal is to help improve communication within and between fields of biomedical research and advance knowledge by using common data elements. The toolbox consists of surveys of Positive Affect, General Life Satisfaction, Emotional Support, Friendship, Loneliness, Perceived Rejection, Perceived Hostility, Self-Efficacy, Sadness, Perceived Stress, Fear, and Anger. Time: The evaluation will take approximately 12-22 minutes to administer.
Comments/Special Instructions	The battery is designed to measure these domains in ages 3 through 85. The NIH Toolbox Motor Battery includes measures of Balance, Dexterity, Endurance, Locomotion and Strength.
Scoring and Psychometric Properties	Scoring: There are individual scores provided for each measure, there are no composite scores. Psychometric Properties:
Rationale/Justification	Sport-Related Concussion-Specific: Strengths: The NIH Toolbox Motor Battery has shown to be methodologically sound and is available in English and Spanish. Has already been validated in TBI population. Can be modified and updated in the future without losing the continuity or comparability of previously collected data (Gershon et al., 2010). Weaknesses: Must be completed by clinician (physician, therapist, nurse, psychologist, social worker). Also, some training is required as well as videotape. TBI-Specific: Strengths:

	Weaknesses:
References	<p>Key References: NIH Toolbox Executive Summary. NIH Toolbox (accessed March 10, 2010).</p> <p>Gershon RC, Cella D, Fox NA, Havlik RJ, Hendrie HC, Wagster MV. Assessment of neurological and behavioural function: the NIH Toolbox. Lancet Neurol. 2010 Feb;9(2):138-9.</p> <p>Additional Reference(s): Quatrano LA, Cruz TH. Future of outcomes measurement: impact on research in medical rehabilitation and neurologic populations. Arch Phys Med Rehabil. 2011 Oct;92(10 Suppl):S7-11.</p> <p>TBI-Specific Reference(s):</p> <p><i>Document last updated June 2019 January 2026</i></p>

NINDS CDE Notice of Copyright NIH Toolbox Odor Identification Test (OIT)

Availability	Please visit this website for more information about this instrument: NIH Toolbox
Classification TBI v3.0 Classification Pending	<p>Supplemental: Acute Hospitalized, Concussion/Mild TBI, Epidemiology, Moderate/Severe TBI; Rehabilitation Traumatic Brain Injury (TBI)</p> <p>Exploratory: Sport-Related Concussion (SRC) Persistent/Chronic (3 months and greater post-concussion)</p>
Short Description of Instrument	<p>The NIH Toolbox Odor Identification Test (OIT) assesses an individual's ability to identify various odors. Participants use scratch 'n' sniff cards and after scratching them one at a time, are asked to identify which of four pictures on the computer screen matches the odor they have just smelled. Participants aged 10–85 are administered nine odor cards, while those aged 3–9 are administered five odor cards. Child participants (ages 3–9 years) are first asked to identify the eight pictures that are used as answer choices, to ensure they can complete the task. Having identified the pictures, they are asked if they have tasted or smelled the objects or foods depicted. The OIT takes approximately 4 to 5 minutes to administer and is recommended for ages 3–85 (NIH, 2012).</p> <p>Sport-Related Concussion-Specific: Rarely reported following mild TBI.</p>
Comments/ Special Instructions	
Scoring and Psychometric Properties	<p>Scoring: Scores are calculated by summing the total number of correct items. Score range, 3–9 = 0 to 5; score range for ages 10 and above = 0 to 9.</p> <p>Psychometric Properties:</p>
Rationale/ Justification	<p>Strengths:</p> <p>Weaknesses:</p>
References	<p>Key Reference(s): NIH. (2012). NIH Toolbox Odor Identification Test. Retrieved 10Dec2025, from http://www.nihtoolbox.org/WhatAndWhy/Sensation/Olfaction/Pages/NIH-Toolbox-Odor-Identification-Test.aspx https://nihtoolbox.org/test/odor-identification-test/</p> <p>Additional References: Cain WS. Sumner's "On testing the sense of smell" revisited. Yale J Biol Med. 1982 Sep-Dec;55(5-6):515-9.</p> <p>Cain WS, Krause RJ. Olfactory testing: rules for odor identification. Neurol Res. 1979;1(1):1-9.</p> <p>Croy I, Zehner C, Larsson M, Zucco GM, Hummel T. Test-retest reliability and validity of the Sniffin' TOM odor memory test. Chem Senses. 2015 Mar;40(3):173-9.</p>

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TBI-Specific Reference(s):

Document last updated ~~March 2018~~ December 2025

NINDS CDE Notice of Copyright Peabody Picture Vocabulary Test 5th Edition (PPVT-5)

Availability	Please visit this website for more information about the instrument: Peabody Picture Vocabulary Test 5th Edition
Classification TBI v3.0 Classification Pending	Supplemental: Mitochondrial Disease (Mito)
Short Description of Instrument	Peabody Picture Vocabulary Test 5th Edition (PPVT-5) is an individually administered norm-referenced instrument that assesses receptive vocabulary for children and adults ages 2 years 6 months to 90 years and older. It measures receptive vocabulary knowledge of various parts of speech (i.e., nouns, verbs, attributes).
Comments/Special Instructions	Co-normed with the Expressive Vocabulary Test – Third Edition (EVT-3) Administration time on average is 11-16 minutes.
Scoring and Psychometric Properties	Scoring: Raw scores are calculated by subtracting the number of errors from the ceiling item. Convert the raw score to a standard score, associated percentile, and age equivalent. Psychometric Properties: Reliability of the PPVT-5 was evidenced using internal consistency, alternate form stability, and test-retest reliability. Validity of the PPVT-5 was evidenced by test content, response processes, relationships with prior version (PPVT-4) and other tests that measure the same constructs, and special group studies.
Rationale/Justification	Strengths: Updated normative data with PPVT-5, easy and quick to administer, iPad and paper administrations available. Weaknesses:
References	Key Reference: Dunn LM, Dunn DM. Peabody Picture Vocabulary Test (5th ed.). Bloomington, MN: NCS Pearson; 2019. Additional Reference: Williams KT. Expressive Vocabulary Test (3rd ed.). Bloomington, MN: NCS Pearson; 2019. TBI-Specific Reference(s): <i>Document last updated March 2024 January 2026</i>

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Pediatric Evaluation of Disability Inventory (PEDI)

Mobility Subscale

Availability	<p>Please visit this website for more information about the instrument:</p> <p>Pediatric Evaluation of Disability Inventory (PEDI) Pediatric Evaluation of Disability Inventory Computer Adaptive Test (PEDI-CAT)</p>
Classification TBI v3.0 Classification Pending	<p>Basic: Acute Hospitalized TBI, Moderate/Severe TBI and Concussion/Mild TBI</p> <p>Supplemental: Cerebral Palsy (CP) and Epidemiologic TBI</p>
Short Description of Instrument	<p>The Pediatric Evaluation of Disability Inventory (PEDI) is a descriptive measure of a child's current functional capabilities performance and tracks changes over time. The measure has three content areas: Self-care, Mobility and Social Function. The self-care sub-domain includes activities such as eating, grooming, dressing, bathing, etc.</p> <p>The PEDI takes between 45 and 60 minutes to administer. Skills commensurate with at least a master's degree level in psychology, education, or related field are recommended for interpretation. The PEDI is a paper based instrument. The computerized PEDI-MCAT provides individual participant patient reports that summarize a participant's patient's functional status and provide a comparison of scores to the norm.</p> <p>The PEDI™ is recommended for children in acute and rehabilitation settings and for post-discharge follow-up. The measure is appropriate for ages 6 months to 7 years.</p>
Comments/Special Instructions	
Scoring and Psychometric Properties	<p>Scoring: Scores for the PEDI range between 0-100, with higher scores indicating less disability.</p> <p>Psychometric Properties:</p>
Rationale/Justification	<p>"The mobility subdomain of this measure was selected as an alternative to the WeeFIM as a core measure of physical functioning in the acute recovery phase." – McCauley et al., 2012</p> <p>Strengths:</p> <p>Weaknesses:</p>
References	<p>Key References:</p> <p>Haley S, Coster W, Ludlow LH, JT, and Andrellos P. (1992). Pediatric evaluation of disability inventory: development, standardization, and administration manual, version 1.0. Trustees of Boston University, Health and Disability Research Institute: Boston, MA.</p> <p>Haley SM, Coster WJ, Dumas HM, Fragala-Pinkman MA, Mood R. 2012. Pediatric Evaluation of Disability Inventory Computer</p>

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Document last updated April 2024 January 2026

NINDS CDE Notice of Copyright Processing Speed Index of the Wechsler Adult Intelligence Scale-Fifth Edition (WAIS-5)

Availability	Please visit this website for more information about the instrument: <u>Processing Speed Index of the Wechsler Adult Intelligence Scale-Fifth Edition</u>
Classification TBI v3.0 Classification Pending	
Short Description of Instrument	The Processing Speed Index is based on 2 subtests of the Wechsler Adult Intelligence Scale-Fifth Edition (WAIS-5), Coding and Symbol Search. Publication Date: 2024 Ages/Grades: Individuals 16-90 years
Comments/Special Instructions	Requires trained examiner to administer and neuropsychologist or psychologist to interpret.
Scoring and Psychometric Properties	Scoring: Psychometric Properties:
Rationale/Justification	Strengths: Weaknesses:
References	Key Reference(s): Wechsler D. Wechsler Adult Intelligence Scale Fifth Edition. (2024). Pearson, San Antonio, TX. Additional Reference(s): TBI-Specific Reference(s): <i>Document last updated January 2026</i>

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SCAN-A and SCAN-C Auditory Processing Disorders Subtests

Availability	<p>Please visit this website for more information about the instruments:</p> <p>The SCAN-A and SCAN-C are Subtests of the SCAN-3 Test for Auditory Processing Disorders</p> <p>Scan A and Scan C</p>
Classification TBI v3.0 Classification Pending	Supplemental: Traumatic Brain Injury (TBI)
Short Description of Instrument	<p>The SCAN-A and SCAN-C test batteries contain auditory processing disorder tests normed for children and adults. The battery includes screening and diagnostic tests.</p> <p>The following tests are recommended:</p> <ul style="list-style-type: none"> Filtered Words Test Auditory Figure-Ground Test Competing Words Test Competing Sentences Test
Comments/Special Instructions	
Scoring and Psychometric Properties	<p>Scoring: Normed scores</p> <p>Psychometric Properties:</p>
Rationale/Justification	<p>Strengths:</p> <p>Weaknesses:</p>
References	<p>Key References:</p> <p>Keith RW. Development and standardization of SCAN-C Test for Auditory Processing Disorders in Children. J Am Acad Audiol. 2000 Sep;11(8):438-45.</p> <p>Keith RW. Development and standardization of SCAN-A: test of auditory processing disorders in adolescents and adults. J Am Acad Audiol. 1995 Jul;6(4):286-92.</p> <p>Keith RW. SCAN-A. Test for auditory processing disorders in adolescents and adults. San Antonio: Psychological Corporation, 1994.</p> <p>Additional References:</p> <p>Dawes P. The SCAN-A in testing for auditory processing disorder in a sample of British adults. Int J Audiol. 2011 Feb;50(2):107-11.</p> <p>Dawes P, Bishop DV. The SCAN-C in testing for auditory processing disorder in a sample of British children. Int J Audiol. 2007 Dec;46(12):780-6.</p> <p>TBI-Specific Reference(s):</p> <p>Document last updated June 2019 January 2026</p>

NINDS CDE Notice of Copyright Symbol Digit Modalities Test

Availability	<p>Please visit this website for more information about the instrument: Symbol Digit Modalities Test</p> <p>The Symbol Digit Modalities Test (SDMT) is currently a part of the Unified Huntington's Disease Rating Scale (UHDRS). A modified version of the SDMT is currently a part of the Brief Repeatable Battery of Neuropsychological Tests for Multiple Sclerosis (Rao, NMSS, 1991).</p> <p>The Symbol Digit Modalities Test is copyrighted by Western Psychological Services.</p>
Classification TBI v3.0 Classification Pending	<p>NeuroRehab Supplemental – Highly Recommended</p> <p>Recommendations for Use: Indicated for studies requiring a measure for processing speed.</p> <p>Supplemental - Highly Recommended: Multiple Sclerosis (MS) Highly recommended for studies involving neuropsychological testing for adult and pediatric MS patients; Huntington's Disease (HD), Highly recommended for cognitive assessments in HD studies.</p> <p>The Symbol Digit Modalities Test is part of the MS Outcomes Assessments Consortium (MSOAC) Battery of tests, which is recommended as Supplemental – Highly Recommended for MS, and includes:</p> <ul style="list-style-type: none"> • Timed 25 Foot Walk • 9-Hole Peg Test • Sloan Low Contrast Letter Acuity • Symbol Digit Modalities Test <p>Each of the measures in the Consortium Battery can be used individually as primary or secondary endpoints.</p> <p>Supplemental: Mitochondrial Disease (Mito), and Sport-Related Concussion (SRC), and Traumatic Brain Injury (TBI)</p>
Short Description of Instrument	<p>Summary/Overview of Instrument: The SDMT measures the time to pair abstract symbols with specific numbers. The test requires elements of attention, visuoperceptual processing, working memory, and cognitive/psychomotor speed.</p> <p>The SDMT is a measure of sustained attention, processing speed, visual scanning, and motor speed. This measure involves a coding key consisting of 9 abstract symbols, each paired with a number ranging from 1 to 9. The participant is required to scan the key and write down the number corresponding to each symbol as fast as possible. The number of correct substitutions within 90 seconds is recorded. In the written version of the test, the participant subject fills in the numbers that correspond to the symbols. In an oral version, the examiner records the numbers spoken by the participant subject.</p> <p>Construct measured: Processing speed, attention. Generic vs. disease specific: Generic.</p>

	<p>Intended use of instrument/purpose of tool: (cross-sectional, longitudinal, diagnostic, etc.): This test has been shown to predict group membership defined by processing speed deficits, such as brain-injured versus control samples, and has been used as a sensitive outcome in studies identifying predictors of longitudinal decline in elders.</p> <p>This measure can be used in ages 8 to 91. It can be used in broad spectrum of TBI severity and type of injuries as long as the subject participant is sufficiently functional to be testable.</p> <p>Means of administration: (paper and pencil, computerized): Written and/or oral. (Classic administration is written form followed by oral form.)</p> <p>Trained examiners. A written or oral version of the test may be administered. When significant upper extremity motor impairment exists, examiners might consider substituting the oral version (or adding it to allow for comparison).</p> <p>Test can be completed in under 5 minutes.</p> <p>Location of administration: (clinic, home, telephone, etc.): Clinical Setting.</p> <p>Intended respondent: Patient. Participant</p> <p># of items: N/A.</p> <p># of subscales and names of sub-scales: N/A.</p>
<p>Comments/Special Instructions</p>	<p>Type of scale used to describe individual items and total/subscale scores (nominal, ordinal, or [essentially] continuous): Continuous.</p> <p>If ordinal or continuous, explain if ceiling or floor effects are to be expected if the measure is used in specific HD Subgroups. No ceiling or floor effects. Individuals with advanced HD may struggle to write legibly due to motor disability.</p> <p>NeuroRehab-Specific: It is broadly used in the literature, has alternate forms and appropriate norms, new norms project completed.</p>
<p>Scoring and Psychometric Properties</p>	<p>Scoring: (include reference to detailed scoring instructions, including calculation of a total score and subscale scores, and any limitations of scale or scoring posed by item nonresponse): The score is the number of correctly coded items from 0–110 in 90 seconds.</p> <p>Standardization of scores to a reference population: (z scores, T scores, etc.): Manual norms have been criticized because they are based on a sample of convenience and were collected in the 1970's. Other published norms are available based on age, education, and sex.</p> <p>If scores have been standardized to a reference population, indicate frame of reference for scoring: (general population, HD subjects, other disease groups, etc.): General population.</p> <p>For multiple sclerosis most clinical research has employed the oral response form exclusively.</p>

	<p>Reliability: Test-retest or intra-interview (within rater) reliability (as applicable): The test demonstrates strong reliability and validity coefficients (6-year interval). Test-retest reliability in other studies ranges between 29 days to 2 years ($r=.70$ to $.91$) (e.g., Smith et al., 1991).</p> <p>Test-retest reliability in MS over two-weeks ranges from 0.85 to 0.98 (Benedict, 2005; Benedict et al., 2012)</p> <p>Inter-interview (between-rater) reliability (as applicable): N/A.</p> <p>Internal consistency: N/A.</p> <p>Statistical methods used to assess reliability: Reliability coefficient.</p> <p>Reliability data from the CAB study will be available by end of 2012 for 100 control, 100 pre-manifest, and 50 early HD subjects.</p> <p>Validity: Content validity: SDMT correlates with oral versions ($r=.78$) (Smith et al., 1991). Construct validity: SDMT correlates well with the Wechsler Digit Symbol subtest ($r=.62$ to $.91$) (Hinton-Bayre et al., 1999).</p>
Rationale/Justification	<p>Strengths: Brief, easy to administer. Oral form allows for valid assessment of processing speed with minimal impact of peripheral motor. Multiple forms available. Updated norms correct for age, sex, and education. A good way to measure processing speed in a more unstructured manner than other processing speed measures. Sensitive to changes in pre-manifest HD in cross-sectional and longitudinal studies. Widely used in multiple sclerosis and for individuals with motor impairment.</p> <p>Weaknesses: More severe motor impairment may influence results, especially on the written version. An oral form of the test is also available, although much less is known about this version when used alone. The manual has old norms and new publications of norms should be used instead (i.e., Strober et al., 2020)</p> <p>Special Requirements for administration: Stopwatch/clock.</p> <p>Administration Time: Less than 5 minutes.</p> <p>Translations available (e.g., Spanish, French, Other languages): Involves only geometric figures and numbers and therefore can be administered to people who do not speak English.</p> <p>Known Relationships to Other Variables: (e.g., gender, education, age, etc.): Performance improves with IQ (Nielsen et al., 1989) and declines with age (Selnes et al., 1991).</p>
References	<p>Key Reference: Smith A. Symbol Digit Modalities Test: Manual. Los Angeles: Western Psychological Services; 1982.</p> <p>Smith A. Symbol Digit Modalities Test: Manual. Los Angeles: Western Psychological Services; 1991.</p>

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	<p>14.</p> <p>Wechsler D. Wechsler adult intelligence scale-III. New York: Psychological Corporation. 1997.</p> <p>TBI-Specific Reference(s):</p> <p><i>Document last updated March 2024 January 2026</i></p>
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NINDS CDE Notice of Copyright Victoria Symptom Validity Test (VSVT)

Availability	Please visit this website for more information about the instrument: Victoria Symptom Validity Test
Classification TBI v3.0 Classification Pending	<p>NeuroRehab Supplemental – Highly Recommended</p> <p>Recommendations for Use: Indicated for studies requiring a performance validity test to detect exaggeration or feigning of cognitive impairment.</p> <p>It is not recommended for use in individuals with known dementia or working memory impairment due to risk of false positive results.</p> <p>Supplemental: Traumatic Brain Injury (TBI)</p>
Short Description of Instrument	<p>The Victoria Symptom Validity Test (VSVT) is a computerized test designed to assess the validity of a participant's patient's cognitive symptoms. It includes 48 items classified as easy or difficult and employs a forced-choice model. The participant's subject's score can be compared to what would be expected based on chance alone.</p> <p>The VSVT has been validated for use in participants patients aged 18 to 72 years and is administered via computer by trained examiners. Administration time is 18-25 minutes.</p>
Comments/Special Instructions	VSVT has norms and is used commonly.
Scoring and Psychometric Properties	<p>Scoring: Two subscores of 0-24 for each item correct.</p> <p>Psychometric Properties: The total item accuracy score has the strongest psychometric properties at an optimal cut-score of ≤ 40 (62% sensitivity/88% specificity). ROC curve analyses for all VSVT indices had statistically significant areas under the curve (AUCs; .73-81). Cut-scores of ≤ 22 for Easy item accuracy and ≤ 40 for Total item accuracy are also used.</p>
Rationale/Justification	<p>Strengths: Psychometrically sound; adequate norms and cut scores.</p> <p>Weaknesses: Length; lack of consensus regarding which index scores to use and which cut scores to use.</p>
References	<p>Key Reference(s): Slick, D., Hopp, G., Strauss, E., & Thompson, G. B. (1997). VSVT: Victoria Symptom Validity Test (Version 1.0). Odessa, Florida: Psychological Assessment Resources.</p> <p>Additional References: Loring DW, Larrabee GJ, Lee GP, Meador KJ. Victoria Symptom Validity Test performance in a heterogenous clinical sample. Clin Neuropsychol. 2007 May;21(3):522-31.</p> <p>Resch ZJ, Webber TA, Bernstein MT, Rhoads T, Ovsiew GP, Soble JR. Victoria Symptom Validity Test: A Systematic Review</p>

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Document last updated ~~January 2022~~ January 2026

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Wide Range Assessment of Memory and Learning, Third Edition (WRAML-3)

Availability	Please visit this website for more information about the instrument: <u>Wide Range Assessment of Memory and Learning, Third Edition</u>
Classification TBI v3.0 Classification Pending	Supplemental: Mitochondrial Disease (Mito)
Short Description of Instrument	<p>The Wide Range Assessment of Memory and Learning, Third Edition (WRAML-3) assesses multiple facets of memory including immediate recall, delayed recall, and recognition and differentiates between visual, verbal, or more global memory deficits.</p> <p>Age range: 5 years to 90 years</p> <p>Immediate Recall Subtests:</p> <ul style="list-style-type: none"> Administration time: 30-35 minutes Six subtests: two visual memory, two verbal memory, two attention/concentration <p>Delayed Recall and Recognition Subtests coincide with the two visual and two verbal memory immediate recall subtests.</p> <p>Supplementary Subtests:</p> <ul style="list-style-type: none"> Visual Working Memory Verbal Working Memory <p>Additional Subtest – Sentence Memory</p>
Comments/Special Instructions	<p>The WRAML-3 has 17 subtests that are organized into 3 groups, Immediate recall, Delayed recall (recognition and working memory) and Additional subtests.</p> <p>Core subtests (n=6): Picture Memory, Story Memory, Design Learning, Verbal Learning, Finger Windows, and Number Letter</p> <p>Supplementary subtests (n=10): Picture Memory, Story Memory, Design Learning, and Verbal Learning delayed recall; Picture Memory, Story Memory Design Learning, and Verbal Learning recognition; Visual and Verbal Working Memory</p> <p>Additional subtest (n=1) Sentence Memory</p>
Scoring and Psychometric Properties	<p>Scoring:</p> <ul style="list-style-type: none"> Hand-scoring and digital scoring options Index Scores – standard scores (Mean=100, SD=15) Subtest Scores – scaled scores (Mean=10, SD=3) <p>The subtests scores used to produce composite index scores with the subtests in brackets include (SpLD Assessment Standards Committee, 2024):</p> <ul style="list-style-type: none"> Visual immediate Memory (Picture Memory and Design Learning) Verbal Immediate Memory Index (Story Memory and Verbal Learning) Attention/concentration Index (Finger Windows and Number Letter) Visual Delayed Index (Picture Memory Delayed and Design Learning Delayed)

	<ul style="list-style-type: none"> • Verbal Delayed Index (Story Memory Delayed and Verbal Learning Delayed) • Visual Recognition Index (Picture Memory Recognition and Design Learning Recognition) • Verbal Recognition Index (Story Memory Recognition and Verbal Learning Recognition) • Working Memory Index (Visual Working Memory and Verbal Working Memory) <p>Psychometric Properties:</p> <ul style="list-style-type: none"> • 2017 normative data sample is a national sample that is representative of the US English-speaking population ages 5-90 years. • Reliability: WRAML-3 is a reliable tool to assess memory <ul style="list-style-type: none"> ▪ Overall average index reliability range from 0.81 to 0.93 ▪ Overall average subtest reliability range from 0.71 to 0.92 ▪ Good evidence for internal consistency ▪ Test-retest scores are highly correlated, reflecting an expected practice effect over a period of 4-5 weeks. ▪ Strong interrater reliability (>.90) • Validity: <ul style="list-style-type: none"> ▪ Strong content, construct, and concurrent validity studies ▪ Good clinical validity in preliminary studies with clinical populations
Rationale/Justification	<p>Strengths:</p> <ul style="list-style-type: none"> • Strong psychometric support • Well-normed • Broad applicability • Flexible administration options • Screener format available – 4 subtests, 25 min. • Brief format available – 2 subtests (design, story), 15 min. • Performance validity indicator built-in (0=acceptable effort, 1=indeterminate effort, 2=questionable effort) <p>Weaknesses:</p> <ul style="list-style-type: none"> • WRAML-3 is not meant to be an exhaustive assessment of memory abilities, it is a useful sampling of important and functionally relevant formal memory tasks. This point is reflected in the manual.
References	<p>Key Reference: Adams W, Sheslow D. <i>Wide Range Assessment of Memory and Learning</i>. 3rd edition. Pearson; 2021.</p> <p>Additional Reference(s): SpLD Assessment Standards Committee. (June 2024) STEC Guidance. The Wide Range Assessment of Memory and Learning 3 (WRAML 3). Retrieved 29Dec2025, from: https://www.sasc.org.uk/media/ynfjzxq1/wraml-3-guidance.pdf</p> <p>TBI-Specific Reference(s): <i>Document last updated March 2024 January 2026</i></p>

Death

[Study Name/ID pre-filled]

Site Name:

Participant ID:

Visit Date:

Visit Name:

1. **Date and time of death: ~~// : (24-hour clock) yyyy m m dd hh m m~~
2. Primary cause of death (and **ICD-10 CM code):

Recorder Signature:

Date:

Death CRF Module Instructions

GENERAL INSTRUCTIONS

This CRF module contains data elements collected in the event of the participant's death while enrolled in the study. It captures the date, time and medical reason death is attributed.

Important note: None of the data elements included on this CRF Module are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies).

Some of the data elements are classified as Supplemental – Highly Recommended (i.e., strongly recommended for all study designs and certain disease conditions or study types), as indicated by asterisks below.

~~**Element is classified as Supplemental – Highly Recommended~~

The remaining data element is classified as Supplemental and should only be collected if the research team considers it appropriate for their study design and type(s).

Additional details regarding classification definitions are available: [Link to be added once available.]

Please see the Data Dictionary for element classifications.

~~Some of the data elements are classified as Basic (i.e., essential information for specified conditions, study types, or designs), as indicated by asterisks below, and should be collected if Acute Hospitalized, Moderate/Severe TBI: Rehabilitation (Death Date and Time; Death cause ICD-10 CM code) or Concussion/Mild TBI (Death cause ICD-10 CM code) studies are performed.~~

~~**Element is classified as Basic~~

~~The remaining data elements are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study.~~

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Date and time of death – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- Primary cause of death –
- Primary cause of death ICD-10 CM code –

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International Classification of Diseases, Tenth ~~Ninth~~ Revision, Clinical Modification (ICD-109-CM):

<http://www.cdc.gov/nchs/icd/icd9cm.htm>

<https://www.cdc.gov/nchs/icd/icd-10-cm/index.html>

Hearing

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Visit Date:

Visit Name:

1. Air conduction result:
☐ Abnormal ☐ Normal
2. Bone conduction result:
☐ Abnormal ☐ Normal
3. Speech reception threshold result:
4. Word discrimination result:
5. Tympanometry result:
☐ Abnormal ☐ Normal
6. Otoacoustic emissions result:
☐ Abnormal ☐ Normal
7. Brainstem auditory evoked potentials result:
☐ Abnormal ☐ Normal
8. Central auditory processing testing result:
☐ Abnormal ☐ Normal
9. Dichotic consonant-vowel test result:
10. Dichotic digits test result:
11. Staggered spondee word test result:
12. Dichotic sentence identification test result:
13. Masking-level differences result:
☐ Abnormal ☐ Normal
14. Binaural fusion test result:
15. Frequency pattern test result:
16. Duration pattern test result:
17. Minimum masking level results:

Recorder Signature:

Date:

Hearing CRF Module Instructions

GENERAL INSTRUCTIONS

TBI v3.0 classification pending.

Additional details regarding classification definitions are available: [Link to be added once available.]

Please see the Data Dictionary for element classifications.

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Air conduction result – Choose one.
- Bone conduction result – Choose one.
- Speech reception threshold result – Result expressed in dB.
- Tympanometry result status – Choose one.
- Otoacoustic emissions result – Choose one.
- Brainstem auditory evoked potentials result – Choose one.
- Central auditory processing testing result – Recommended central auditory processing tests include Random-Gap Detection Test, Time-Compressed Sentence Test, Filtered Words Tests, Auditory Figure-Ground Tests, Dichotic CV Test, Dichotic Digits Test, Staggered Spondee Word Test, Competing Words Test of SCAN-C and SCAN-A, Competing Sentences Test of SCAN-C and SCAN-A, Dichotic Sentence Identification Test, Masking-Level Differences, Binaural Fusion Test, Frequency Pattern Test, and Duration Pattern Test.
- Dichotic consonant-vowel test result – Record the dichotic consonant-vowel test result as a percentage.
- Dichotic digits test result – Record the dichotic digits test result as a percentage.
- Staggered spondee word test result – Record the staggered spondee word test result as a percentage.
- Dichotic sentence identification test result – Record the dichotic sentence identification test result as a percentage.
- Masking-level differences result – Choose one.
- Binaural fusion test result – Record the binaural fusion test result threshold in msec.
- Frequency pattern test result – Record the frequency pattern test result as a percentage.
- Duration pattern test result – Record the duration pattern test result as a percentage.
- Minimum masking level results – The minimum masking level (MML) is used to measure tinnitus and is expressed in dB sensation level (SL).

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Hearing CRF Module Instructions

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Neurological Assessment: GCS and Pupils

[Study Name/ID pre-filled]

Site Name:

Participant ID:

Visit Name:

Visit Date:

GLASGOW COMA SCALE OR PEDIATRIC GLASGOW COMA SCALE

The Glasgow Coma Scale is classified as Disease Core and is strongly recommended for all TBI clinical studies. It should be completed whenever this CRF is completed. Additional information regarding the Glasgow Coma Scale and Pediatric Glasgow Coma Scale can be found here: [Link to be added once available.]

1. Scale used:

- ☐ Glasgow Coma Scale (GCS)
☐ Pediatric Glasgow Coma Scale (PGCS)

2. Glasgow Coma Scale assessment date and time:

3. Context of Glasgow Coma Scale assessment (Choose one):

- ☐ At injury scene
☐ At arrival in Emergency Department
☐ Post-resuscitation in Emergency Department
☐ At follow-up assessment

~~**GCS confounders type (Choose all that apply):~~

- | | |
|--|--|
| <input type="checkbox"/> GCS Accurate | <input type="checkbox"/> Hypothermia |
| <input type="checkbox"/> Hypoxia/hypotension | <input type="checkbox"/> C-spine injury |
| <input type="checkbox"/> Paralytic | <input type="checkbox"/> Sedation |
| <input type="checkbox"/> Alcohol/drugs of abuse | <input type="checkbox"/> Unknown |

4. Are there confounders present that affect Glasgow Coma Scale assessment (Choose all that apply)?

- ☐ None
☐ Unknown
☐ Sedation/paralytics
☐ Intubation/tracheostomy
☐ Language barrier/aphasia
☐ Alcohol/drug intoxication
☐ Pre-existing neurologic deficits
☐ Severe facial trauma/edema
☐ Shock/hypothermia/metabolic derangements

PUPIL ASSESSMENT

5. Pupil reactivity assessment date and time:

6. How was pupil reactivity measured? (Choose one)

- ☐ Manually (if selected answer Questions 9-12)
☐ Using automated pupillometry (if selected answer Questions 7-12)

7. ~~**Left pupil measurement (mm):~~

- ☐ ~~Untestable~~ ☐ ~~Unknown~~

8. ~~**Right pupil measurement (mm):~~

- ☐ ~~Untestable~~ ☐ ~~Unknown~~

9. ~~**Left pupil shape:~~

- ☐ ~~Round~~ ☐ ~~Oval~~ ☐ ~~Unknown~~

Neurological Assessment: GCS and Pupils

[Study Name/ID pre-filled]

Site Name:

Participant ID:

10. **Right pupil shape:

☐ Round ☐ Oval ☐ Unknown

11. **Left pupil reactivity (Choose one):

☐ Brisk ☐ Sluggish ☐ Nonreactive ☐ Untestable ☐ Unknown

12. **Right pupil reactivity (Choose one):

☐ Brisk ☐ Sluggish ☐ Nonreactive ☐ Untestable ☐ Unknown

Recorder Signature:

Date:

Neurological Assessment: GCS and Pupils CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements that are collected to assess severity of the injury using the Glasgow Coma Scale and an examination of the participant's pupils.

TBI v3.0 classification pending.

Additional details regarding classification definitions are available: [Link to be added once available.]

Please see the Data Dictionary for element classifications.

~~Important note: Most of the data elements are classified as Core (i.e., strongly recommended for all TBI clinical studies to collect) or Basic (i.e., essential information for specified conditions, study types, or designs), as indicated by asterisks below, and should be collected if specified studies are performed.~~

~~*Element is classified as Core:~~

~~Glasgow Coma Scale (GCS) – Eye response~~

~~Glasgow Coma Scale (GCS) – Motor response~~

~~Glasgow Coma Scale (GCS) – Verbal response~~

~~Glasgow Coma Scale (GCS) – Total score~~

~~Pediatric Glasgow Coma Scale (PGCS) – Eye response~~

~~Pediatric Glasgow Coma Scale (PGCS) – Motor response~~

~~Pediatric Glasgow Coma Scale (PGCS) – Verbal response~~

~~Pediatric Glasgow Coma Scale (PGCS) – Total score~~

~~**Element is classified as Basic for Acute Hospitalized studies:~~

~~Glasgow Coma Scale (GCS) – Confounders type~~

~~Left pupil reactivity~~

~~Right pupil reactivity~~

~~**Element is classified as Basic for Concussion/Mild TBI studies:~~

~~Glasgow Coma Scale (GCS) – Confounders type~~

~~**Element is classified as Basic for Moderate/Severe TBI: Rehabilitation studies:~~

~~Left pupil measurement~~

~~Right pupil measurement~~

~~Left pupil shape~~

~~Right pupil shape~~

~~Left pupil reactivity~~

~~Right pupil reactivity~~

~~For other study types these CDEs are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study.~~

~~Glasgow Coma Scale (GCS) – Scale type is Supplemental for all study types.~~

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Glasgow Coma Scale (GCS) or Pediatric Glasgow Coma Scale (PGCS) – No instructions available.

Neurological Assessment: GCS and Pupils CRF Module Instructions

- Glasgow Coma Scale assessment date and time – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- ~~GCS confounders type – Choose one.~~
- Are there confounders present that affect Glasgow Coma Scale assessment? – Choose all that apply.
- Pupil reactivity assessment date and time – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- How was pupil reactivity measured? – Choose one.
- Left pupil measurement – Pupil measurement recorded in millimeters (mm). Acceptable range is 1-10mm. This element is recommended for pediatric studies. Record resting pupil diameter in millimeters under the standard ambient lighting condition defined in the study protocol (for example, typical room lighting before any light stimulus is applied).
- Right pupil measurement – Pupil measurement recorded in millimeters (mm). Acceptable range is 1-10mm. This element is recommended for pediatric studies. Record resting pupil diameter in millimeters under the standard ambient lighting condition defined in the study protocol (for example, typical room lighting before any light stimulus is applied).
- Left pupil shape – Choose one. Recommend collection at least at study hospital admission/discharge and protocol milestones. This element is recommended for pediatric studies.
- Right pupil shape – Choose one. Recommend collection at least at study hospital admission/discharge and protocol milestones. This element is recommended for pediatric studies.
- Pupil shape should be recorded during manual or automated pupillometry. If automated pupillometry is used, shape should still be noted based on device output or clinical observation.
- Left pupil reactivity – Choose one. Ideally, pupillometry should be conducted in dim light for reactivity to be detected.
- Right pupil reactivity – Choose one. Ideally, pupillometry should be conducted in dim light for reactivity to be detected.

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Neurological Assessment: GCS and Pupils CRF Module Instructions

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Teasdale G, Jennett B. Assessment of coma and impaired consciousness. A practical scale. Lancet. 1974 Jul 13;2(7872):81-4.

Neurological Assessment: LOC, PTA, and AOC

[Study Name/ID pre-filled]

Site Name:

Participant ID:

Visit Date:

Visit Name:

LOSS OF CONSCIOUSNESS

1. **Did participant/~~subject~~ experience loss of consciousness? (Choose one)

☐ Yes ☐ No ☐ Suspected ☐ Unknown

2. *Duration of loss of consciousness (Choose one):

<input type="checkbox"/> None	<input type="checkbox"/> 1-24 hours	<input type="checkbox"/> No return of consciousness prior to death or discharge
<input type="checkbox"/> <1 minute	<input type="checkbox"/> 1-7 days	<input type="checkbox"/> Unknown
<input type="checkbox"/> 1-29 minutes	<input type="checkbox"/> >7 days	
<input type="checkbox"/> 30-59 minutes		

3. **How the loss of consciousness was verified (Choose one):

☐ Self-report ☐ Witness ☐ Clinical interview ☐ Medical chart ☐ Not available ☐ Unknown

POST-TRAUMATIC AMNESIA

4. **Did participant/~~subject~~ experience post-traumatic amnesia? (Choose one)

☐ Yes ☐ No ☐ Suspected ☐ Unknown

5. *Duration of post-traumatic amnesia (Choose one):

<input type="checkbox"/> None	<input type="checkbox"/> 1-24 hours	<input type="checkbox"/> 29-70 days
<input type="checkbox"/> <1 minute	<input type="checkbox"/> 1-7 days	<input type="checkbox"/> >70 days
<input type="checkbox"/> 1-29 minutes	<input type="checkbox"/> >7 8-14 days	<input type="checkbox"/> N/A (e.g., Death)
<input type="checkbox"/> 30-59 minutes	<input type="checkbox"/> 15-28 days	<input type="checkbox"/> Unknown

6. How the post-traumatic amnesia was verified (Choose one):

☐ Self-report ☐ Witness ☐ Clinical interview ☐ Medical chart ☐ Not available ☐ Unknown

ALTERATION OF CONSCIOUSNESS

7. Did participant/~~subject~~ experience alteration of consciousness? (Choose one)

☐ Yes ☐ No ☐ Suspected ☐ Unknown

8. Duration of alteration of consciousness (Choose one):

<input type="checkbox"/> None	<input type="checkbox"/> 30-59 minutes	<input type="checkbox"/> >7 days
<input type="checkbox"/> <1 minute	<input type="checkbox"/> 1-24 hours	<input type="checkbox"/> Unknown
<input type="checkbox"/> 1-29 minutes	<input type="checkbox"/> 1-7 days	

9. How the alteration of consciousness was verified (Choose one):

☐ Self-report ☐ Witness ☐ Clinical interview ☐ Medical chart ☐ Not available ☐ Unknown

Additional Supplemental Elements: These elements may be included if relevant to the study. For additional details like permissible values, see the data dictionary

10. Lucid interval indicator:

☐ Yes ☐ No ☐ Suspected ☐ Unknown

Recorder Signature:

Date:

Neurological Assessment: LOC, PTA, and AOC CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements related to neurological assessment of the study participant regarding loss of consciousness (LOC), post-traumatic amnesia (PTA) and alternation of consciousness (AOC).

TBI v3.0 classification pending.

Additional details regarding classification definitions are available [Link to be added once available.]

Please see the Data Dictionary for element classifications.

~~Important note: Most of the data elements are classified as Core (i.e., strongly recommended for all TBI clinical studies to collect) or Basic (i.e., essential information for specified conditions, study types, or designs), as indicated by asterisks below, and should be collected if specified studies are performed.~~

~~*Element is classified as Core:~~

~~Loss of consciousness duration range~~

~~Post traumatic amnesia duration range~~

~~**Element is classified as Basic for Acute Hospitalized, Concussion/Mild TBI, and Moderate/Severe TBI: Rehabilitation studies:~~

~~Loss of consciousness indicator~~

~~Loss of consciousness verification type~~

~~Post traumatic amnesia verify type~~

~~Alteration consciousness indicator~~

~~Alteration of consciousness duration range~~

~~Alteration of consciousness verify type~~

~~**Element is classified as Basic for Comprehensive, Acute Hospitalized, Concussion/Mild TBI, and Moderate/Severe TBI: Rehabilitation studies:~~

~~Post traumatic amnesia indicator~~

~~For other study types these CDEs are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study.~~

~~Lucid interval indicator is Supplemental for all study types.~~

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Did participant/subject experience loss of consciousness? – Choose one.
'Suspected' should be used when there is indirect evidence of loss of consciousness (e.g., witnessed fall, post-event confusion) but no definitive confirmation.
- Duration of loss of consciousness – Choose one.
Use '> 7 days' when the participant eventually regained consciousness after 7 days. Use 'No return of consciousness prior to death or discharge' only when the participant never regained consciousness before death or study-hospital discharge.
- How the loss of consciousness was verified – Choose one.
Use 'Not available' when the source category does not exist for the participant (e.g., no witness). Use 'Unknown' when the source exists but documentation does not provide the information.
- Did participant/subject experience post-traumatic amnesia? – Choose one.

Neurological Assessment: LOC, PTA, and AOC CRF Module Instructions

- Duration of post-traumatic amnesia – Choose one. Researchers should indicate the post-traumatic amnesia category that corresponds with the participant's hospital length of stay + 1 day. 0-14 days (Moderate), 15-18 days (Moderate-Severe), 29-70 days (Severe) and >70 days (Extremely Severe). Use '> 70 days' when the participant eventually regained memory continuity after seventy days. Use 'N/A (e.g., death)' only when the participant did not survive to a point where PTA resolution could be assessed.
- How the post-traumatic amnesia was verified – Choose one.
Use 'Not available' when the source category does not exist for the participant (e.g., no witness). Use 'Unknown' when the source exists but documentation does not provide the information.
- Did participant/subject experience alteration of consciousness? – Choose one.
- Duration of alteration of consciousness – Choose one. Recommend collection at least on date of TBI. Use the duration category that best represents the period of altered consciousness. Use 'Unknown' when no reliable information is available. ~~Depending on the level of detail available or required, use one of the following classification schemes: Core: None; < 1 hour; 1-24 hours; > 24 hours Intermediate/Advanced: None; <1 minute; 1-29 minutes; 30-59 minutes; 1-24 hours; 1-7 days; > 7 days; Unknown A period of alteration of consciousness is a key measure in determining diagnosis of mTBI and its differentiation from more severe TBI.~~
- How the alteration of consciousness was verified – Choose one.
Use 'Not available' when the source category does not exist for the participant (e.g., no witness). Use 'Unknown' when the source exists but documentation does not provide the information.
- Lucid interval indicator – Choose one. Select 'Yes' when a temporary recovery of consciousness occurs between two periods of impaired consciousness after the injury. Use 'Suspected' only when documentation suggests but does not confirm this pattern. This additional Supplemental element may be included if relevant to the study.

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Neurological Assessment: LOC, PTA, and AOC CRF Module Instructions

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Neurological Assessment: TBI Symptoms and Signs

[Study Name/ID pre-filled]

Site Name:

Participant ID:

Visit Date:

Visit Name:

1. Orientation to person result: ☐ Abnormal ☐ Normal
2. Orientation to place result: ☐ Abnormal ☐ Normal
3. Orientation to time result: ☐ Abnormal ☐ Normal

Recorder Signature:

Date:

Neurological Assessment: TBI Symptoms and Signs CRF Module Instructions

GENERAL INSTRUCTIONS

TBI v3.0 classification pending.

Additional details regarding classification definitions are available: [Link to be added once available.]

Please see the Data Dictionary for element classifications.

~~All of the data elements are classified as Supplemental for Comprehensive, Acute Hospitalized, Epidemiology, and Moderate/Severe TBI: Rehabilitation studies and should only be collected if the research team considers them appropriate for their study.~~

~~Some of the data elements are classified as Basic (i.e., essential information for specified conditions, study types, or designs), as indicated by asterisks below, for Concussion/Mild TBI studies.~~

~~**Element is classified as Basic:~~

- ~~• Does participant/subject display the following TBI symptom or sign?~~
- ~~• TBI symptom Other, specify~~
- ~~• TBI symptom indicator~~

~~The remaining data elements are classified as Supplemental (i.e., non-Core) for Concussion/Mild TBI studies and should only be collected if the research team considers them appropriate for their study.~~

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Orientation to person result – Choose one. Add date stamp for when assessed. Recommend collection at least on date of TBI. This element is recommended for pediatric studies.
- Orientation to place result – Choose one. Add date stamp for when assessed. Recommend collection at least on date of TBI. This element is recommended for pediatric studies.
- Orientation to time result – Choose one.

REFERENCES

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Post-Discharge Status

[Study Name/ID pre-filled]

Site Name:

Participant ID:

Visit Date:

Visit Name:

1. **Vital status on discharge (Choose one):

- ☐ Alive
- ☐ Dead
- ☐ Unknown

2. **Return to work or school (Choose one):

- ☐ Returned to previous level
- ☐ Different work or school
- ☐ Did not return to work or school
- ☐ Unknown
- ☐ Same work or school, reduced level
- ☐ Only in sheltered environment
- ☐ N/A

3. **Type of residence (Choose one):

- ☐ Rehabilitation center
- ☐ Nursing home
- ☐ N/A - ~~patient~~ participant died
- ☐ Unknown
- ☐ Hospital
- ☐ Home
- ☐ **Other, specify:

Recorder Signature:

Date:

Post-Discharge Status CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements that capture the participant's course of treatment post-discharge.

Important note: None of the data elements included on this CRF Module are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies).

All the data elements are classified as Supplemental – Highly Recommended (i.e., strongly recommended for all study designs and certain disease conditions or study types).

Additional details regarding classification definitions are available: [Link to be added once available.]

Please see the Data Dictionary for element classifications.

~~All of the data elements are classified as Basic (i.e., essential information for specified conditions, study types, or designs), as indicated by asterisks below, for at least one study type.~~

~~**Element is classified as Basic~~

~~Additional classification information is provided below:~~

- ~~• Vital status on discharge – Classified as Basic for Acute Hospitalized studies~~
- ~~• Return to work or school – Classified as Basic for Epidemiology studies~~
- ~~• Type of residence – Classified as Basic for Epidemiology and Moderate/Severe TBI: Rehabilitation studies~~
- ~~• Type of residence other, specify – Classified as Basic for Epidemiology and Moderate/Severe TBI: Rehabilitation studies~~

~~For other study types, the data elements are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study.~~

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Vital status on discharge – Choose one.
- Return to work or school – Choose one. Recommend collection at least at end of initial medical care. Add date stamp for when assessed.
- Type of residence – Choose one. Add date and time stamp for when assessed.

REFERENCES

Post-Traumatic Epilepsy Screening Form

[Study Name/ID pre-filled]

Site Name:

Participant ID:

Visit Date:

Visit Name:

~~Patient-Participant~~/caregiver interview:

1. ~~Have you/your family member~~ Has the participant had or has anyone ever told ~~the participant you that you/~~ they had any of the following:
 - a. Uncontrolled movements of part or all of the body such as twitching, jerking, shaking or going limp, lasting about 5 minutes or less?
☐ Yes ☐ No ☐ Unknown
 - b. An unexplained change in mental state or level of awareness; or an episode of "spacing out" which ~~you/your family member~~ the participant could not control, lasting about 5 minutes or less?
☐ Yes ☐ No ☐ Unknown
 - c. Any other type of repeated unusual attacks or convulsions lasting about 5 minutes or less?
☐ Yes ☐ No ☐ Unknown
2. Has anyone ever told ~~you that you/your family member~~ the participant they have seizure(s) or epilepsy?
☐ Yes ☐ No ☐ Unknown

If the answer to any of the questions above is YES, proceed to the following questions:

1. Which of the following sources of information were queried? (Choose all that apply):
☐ ~~Patient-Participant~~ ☐ Caregiver ☐ Medical record
2. Has the participant had seizures or epilepsy prior to the traumatic brain injury?
☐ Yes ☐ No ☐ Unknown
3. Has the participant been diagnosed with epilepsy, a seizure disorder, or a single seizure after the date of the traumatic brain injury diagnosis?
☐ Yes ☐ No ☐ Unknown
4. Did seizure(s) occur later than seven days after the date of the traumatic brain injury?
☐ Yes ☐ No ☐ Unknown
5. Date of diagnosis:
6. Who gave this diagnosis?

<input type="checkbox"/> Neurosurgeon	<input type="checkbox"/> Pediatrician
<input type="checkbox"/> Neurologist	<input type="checkbox"/> Psychiatrist
<input type="checkbox"/> Pediatric Neurologist	<input type="checkbox"/> Psychologist
<input type="checkbox"/> Primary Care Physician	<input type="checkbox"/> Nurse Practitioner
7. Has the ~~patient-participant~~ received medication for seizures or epilepsy?
☐ Yes ☐ No ☐ Unknown

Form 1401-21 Rev M-012910 (Modified 12/17/2013 by NINDS Epilepsy CDE team for epilepsy screening data sets)

Recorder Signature:

Date:

Post-Traumatic Epilepsy Screening Form CRF Module Instructions

GENERAL INSTRUCTIONS

The Post-Traumatic Epilepsy Screening form screens for post-traumatic epilepsy or seizures.

TBI v3.0 classification pending.

Additional details regarding classification definitions are available [Link to be added once available.]

Please see the Data Dictionary for element classifications.

~~All of the data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study.~~

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Uncontrolled movements of part or all of the body such as twitching, jerking, shaking or going limp, lasting about 5 minutes or less? – Use this response option when the reported episode was brief (typically under five minutes), even if the exact duration was not timed. Use 'Unknown' when no estimate of duration is available.
- An unexplained change in mental state or level of awareness; or an episode of "spacing out" which ~~you/your family member~~ the participant could not control, lasting about 5 minutes or less? –
- Any other type of repeated unusual attacks or convulsions lasting about 5 minutes or less? –
- Has anyone ever told ~~you that you/your family member~~ the participant they have seizure(s) or epilepsy? –
- Which of the following sources of information were queried? – Choose all that apply.
- Has the participant had seizures or epilepsy prior to the traumatic brain injury? –
- Has the participant been diagnosed with epilepsy, a seizure disorder, or a single seizure after the date of the traumatic brain injury diagnosis? –
- Did seizure(s) occur later than seven days after the date of the traumatic brain injury? –
- Date of diagnosis – Record the earliest documented clinical diagnosis of epilepsy, seizure disorder, or single unprovoked seizure made after the TBI. Do not record pre-TBI diagnosis dates here. If no post-TBI diagnosis date is documented, code the date as unknown. Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- Who gave this diagnosis? –
- Has the ~~patient~~ participant received medication for seizures or epilepsy? –

REFERENCES

Screening Tools

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Visit Date:
Visit Name:

1. Since ~~your~~ the participant's brain injury, ~~have you~~ has the participant had a problem with dizziness, lightheadedness, feeling as if you are going to pass out or faint, unsteadiness, ~~loss of coordination~~, or imbalance?
☐ Yes ☐ No
2. Since ~~your~~ the participant's brain injury, has ~~your~~ the participant's hearing been worse in either ear?
☐ ~~Yes~~
☐ Yes, worse in both ears
☐ Yes, worse in left ear
☐ Yes, worse in right ear
☐ No
3. Since ~~your~~ the participant's brain injury, has ~~your~~ the participant's ability to taste, or smell changed?
☐ Yes ☐ No
4. Since ~~your~~ the participant's brain injury, ~~have you~~ has the participant been bothered by ringing, roaring, buzzing, or other sounds in ~~your~~ the ears or head that last for 5 minutes or more?
☐ Yes ☐ No
5. Since ~~your~~ the participant's brain injury, ~~have you~~ has the participant had any problems with ~~your~~ their voice?
☐ Yes ☐ No
6. Since ~~your~~ the participant's brain injury, ~~have you~~ has the participant had any problems with ~~your~~ swallowing?
☐ Yes ☐ No
7. Since ~~your~~ the participant's brain injury, ~~have you~~ has the participant had any problems with ~~your~~ speech?
☐ Yes ☐ No
8. Since ~~your~~ the participant's brain injury, ~~have you~~ has the participant had any problems with ~~your~~ language (e.g., understanding others, verbal expression, reading, writing)?
☐ Yes ☐ No

Recorder Signature:

Date:

Screening Tools CRF Module Instructions

GENERAL INSTRUCTIONS

Important note: None of the data elements included on this CRF Module are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies).

All the data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study design and type(s).

Additional details regarding classification definitions are available: [Link to be added once available.]

Please see the Data Dictionary for element classifications.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Since the participant's brain injury, has the participant had a problem with dizziness, lightheadedness, feeling as if you are going to pass out or faint, unsteadiness, loss of coordination, or imbalance? –
- Since the participant's brain injury, has the participant's hearing been worse in either ear? –
- Since the participant's brain injury, has the participant's ability to taste, or smell changed? –
- Since the participant's brain injury, has the participant been bothered by ringing, roaring, buzzing, or other sounds in the ears or head that last for 5 minutes or more? –
- Since participant's brain injury, has the participant had any problems with their voice? –
- Since participant's brain injury, has the participant had any problems with swallowing? –
- Since the participant's brain injury, has the participant had any problems with speech? –
- Since participant's brain injury, has the participant had any problems with language (e.g., understanding others, verbal expression, reading, writing)? –

REFERENCES

Study Discontinuation/Completion

[Study Name/ID pre-filled]

Site Name:

Participant ID:

Visit Date:

Visit Name:

1. Indicates that participant/~~subject~~ prematurely discontinued study intervention:

☐ Yes ☐ No ☐ Unknown

2. Primary reason participant/~~subject~~ discontinued study intervention (Choose all that apply):

☐ Adverse event

☐ Other clinical decision (e.g., investigator decision, primary care provider decision, etc.) OR other reason specified by the protocol (i.e., institutionalization, pregnancy, etc.)

☐ Death

☐ Participant's/~~Subject's~~ decision (e.g., unwilling/unable to commit time and/or resources, moved from area, etc.)

☐ Lost to follow-up

☐ Other, specify:

Recorder Signature:

Date:

Study Discontinuation/Completion CRF Module Instructions

GENERAL INSTRUCTIONS

Important note: None of the data elements included on this CRF Module are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies).

All the data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study design and type(s).

Additional details regarding classification definitions are available: [Link to be added once available.]

Please see the Data Dictionary for element classifications.

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Indicates that participant/~~subject~~ prematurely discontinued study intervention – Choose one.
- Primary reason participant/~~subject~~ discontinued study intervention – Choose all that apply.

REFERENCES