

NIH Resources

The NINDS also strongly encourages researchers to use these NIH developed materials for NINDS-sponsored research, when appropriate. Utilization of these resources will enable greater consistency for NINDS-sponsored research studies. Some of these tools are free of charge.

- National Institutes of Health (NIH) Toolbox
- Quality of Life in Neurological Disorders (Neuro-QOL)
- Patient-Reported Outcomes Measurement Information System (PROMIS)

Suicidal Ideation

Investigators should review the FDA's "Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials" for the most up-to-date information about suicidal ideation and behavior. One scale that FDA suggests is the Columbia Suicide Severity Rating Scale (C-SSRS) (available at Columbia Suicide Severity Rating Scale Website).

Subgroup	Recommendations
Sport-Related Concussion	These instruments and elements are recommended for use in all Sport-Related Concussion (SRC) studies:
	Core instruments:
	One of the following Cognitive Assessment measures should be collected: Automated Neuropsychological Assessment Metrics (ANAM), Axon Sports Computerized Cognitive Assessment Tool (CCAT), CNS Vital Signs, Immediate Post- Concussion Assessment and Cognitive Testing (ImPACT). Please note that these could be replaced by a pen or paper battery under the direction of a neuropsychologist.
	One of the following Post-concussive/mild TBI related Symptoms measures should be collected: Health and Behavior Inventory (HBI), Concussion Symptom Inventory (PCSI), Post Concussion Symptoms Scale (PCSS), Rivermead Post-Concussive Symptoms Questionnaire (RPQ).
	Acute: Balance Error Scoring System (BESS)
	Acute: One of the following Post-concussive/mild TBI Related Symptoms should be collected: Child Sport Concussion Assessment Tool (Child-SCAT), Post Concussion Symptom Inventory (PCSI), Post Concussion Symptoms Scale (PCSS), Sport Concussion Assessment Tool (SCAT-3) _or 5, or Rivermead Post-Concussive Symptoms Questionnaire (RPQ).
	Subacute: One of the following Post-concussive/mild TBI Related Symptoms should be collected: Health and Behavior Inventory (HBI), Post Concussion Symptom Inventory (PCSI), Post Concussion Symptoms Scale (PCSS), or Rivermead Post-Concussive Symptoms Questionnaire (RPQ).



Subgroup	Recommendations
	Persistent/Chronic: One of the following Post-concussive/mild TBI Related Symptoms should be collected: Health and Behavior Inventory (HBI), Post Concussion Symptom Inventory (PCSI), Post Concussion Symptoms Scale (PCSS), or Rivermead Post-Concussive Symptoms Questionnaire (RPQ).
	Supplemental-Highly Recommended: Acute: Brief Symptom Inventory 18 Item (BSI-18), Center for Epidemiologic Studies Depression Scale (CES-D), Children's Orientation and Amnesia Test (COAT), Controlled Oral Word Association Test (COWAT), Health and Behavior Inventory (HBI), Hopkins Verbal Learning Test -Revised (HVLT-R), Trail Making Test (TMT), Wechsler Adult Intelligence Scale (WAIS-IV), Wechsler Intelligence Scale for Children (WISC-V)
	Subacute: Controlled Oral Word Association Test (COWAT), Dizziness Handicap Inventory (DHI), Hopkins Verbal Learning Test -Revised (HVLT-R), Pediatric Quality of Life Inventory (PEDSQL), Standardized Assessment of Concussion (SAC), Trail Making Test (TMT), Wechsler Adult Intelligence Scale (WAIS-IV), Wechsler Intelligence Scale for Children (WISC-V), VOMS (Brief Vestibular/Ocular Motor Screening Assessment).
	Persistent/Chronic: Controlled Oral Word Association Test (COWAT), Dizziness Handicap Inventory (DHI), Dynamic Gait Index, Functional Gait Assessment, Hopkins Verbal Learning Test -Revised (HVLT-R), Trail Making Test (TMT), Wechsler Adult Intelligence Scale (WAIS-IV), Wechsler Intelligence Scale for Children (WISC-V).
	Core and Supplemental-Highly Recommended elements: See Start-Up Resource Listing document (SRC Start-Up Resource Listing)
NIH Resources	Core: None Supplemental: National Institutes of Health (NIH) Toolbox, Patient-Reported Outcomes Measurement Information System (PROMIS); Quality of Life in Neurological Disorders (Neuro-QOL)
Summary Documents	Acute Subgroup Working Group Summary, Subacute Subgroup Working Group Summary, and Persistent/Chronic Working Group Summary
Participant Characteristics; Demographics	Core: General Core Supplemental – Highly Recommended: None
	Supplemental: Demographic
	Exploratory: None
Participant	Core: None



Subgroup	Recommendations
Characteristics; Social Status	Supplemental – Highly Recommended: None
	Supplemental: Socioeconomic Status
	Exploratory: None
Participant History and Family History;	Core: None
General Health	Supplemental – Highly Recommended: None
History	Supplemental: Personal Medical History; Participant and Family Psychological History; Concussion History; Migraine History; Substance Use
	Exploratory: None
History of Disease/Injury	Core: None
Related Events; History of	Supplemental – Highly Recommended: None
Disease/Injury Event	Supplemental: Injury Report; Return to Play
	Exploratory: None
Assessment and Examinations;	Core: None
Physical Examinations	Supplemental – Highly Recommended: None
	Supplemental: Clinical Examination
	Exploratory: None
Assessments and Examinations;	Core: None
Vital Signs	Supplemental – Highly Recommended: None
	Supplemental: Vital Signs
	Exploratory: None
Assessments and Examinations;	Core: None
Laboratory Tests and Biospecimens /	Supplemental – Highly Recommended: None
Biomarkers	Supplemental: Active Saliva Collection; DNA Guidelines For Genomic Analyses; Passive Saliva Collection; Serum Collection Protocol; Plasma and Serum Guidelines for Proteomic Analysis; TBI Biospecimen Collection Protocol



•	Recommendations
Subgroup	Recommendations
	Exploratory: None
Assessments and Examinations;	Core: None
Imaging Diagnostic	Supplemental – Highly Recommended: None
	Supplemental: Imaging
	Exploratory: None
Treatment /Intervention Data;	Core: None
Drugs	Supplemental – Highly Recommended: None
	Supplemental: Medications
	Exploratory: None
Treatments / Intervention Data;	Core: None
Therapies	Supplemental – Highly Recommended: None
	Supplemental: Treatment and Interventions
	Exploratory: None
Outcomes and End Points; Academic	Core: None
	Supplemental – Highly Recommended: None
	Supplemental: Wechsler Test of Adult Reading (Acute, Subacute, and Persistent Chronic timeframes); Test of Premorbid Functioning (TOPF) (Acute, Subacute, and Persistent Chronic timeframes)
	Exploratory: None
Outcomes and End Points; Behavioral	Core: None
Function	Supplemental – Highly Recommended: None
	Supplemental: None
	Exploratory: Child Behavior Checklist (CBCL) (<i>Acute, Subacute, and Persistent Chronic timeframes</i>); Frontal Systems Behavior Scale (FrSBe) (<i>Acute, Subacute, and Persistent Chronic timeframes</i>)



Subgroup	Recommendations
Outcomes and End Points;	Core: None
Effort/Symptom Validity	Supplemental – Highly Recommended: None
	Supplemental: Medical Symptom Validity Test (<i>Subacute and Persistent Chronic timeframes</i>); Test of Memory Malingering (<i>Subacute and Persistent Chronic timeframes</i>)
	Exploratory: Test of Memory Malingering (Acute); Word Memory Test (Subacute and Persistent/Chronic timeframes)
Outcomes and End Points; Family and	Core: None
Environment	Supplemental – Highly Recommended: None
	Supplemental: Conflict Behavior Questionnaire (CBQ)/Interaction Behavior Questionnaire (IBQ) (Persistent/Chronic timeframe); Family Assessment Device (FAD) (Persistent/Chronic timeframe);
	Exploratory: Child and Adolescent Scale of Environment (CASE) (Subacute and Persistent/Chronic timeframes); Conflict Behavior Questionnaire (CBQ)/Interaction Behavior Questionnaire (IBQ) (Subacute timeframe); Family Assessment Device (FAD) (Subacute timeframe); Family Burden of Injury Interview (self-report or interview) (Subacute and Persistent/Chronic timeframes); Family History Research Diagnostic Criteria (FHRDC) (Subacute and Persistent/Chronic timeframes)
Outcomes and End Points; Global	Core: None
Outcomes	Supplemental – Highly Recommended: None
	Supplemental: None
	Exploratory: Mayo-Portland Adaptability Inventory (MPAI-4) – Adult (<i>Subacute and Persistent/Chronic timeframes</i>); Mayo-Portland Adaptability Inventory (MPAI-4) – Pediatric (<i>Subacute and Persistent/Chronic timeframes</i>)
Outcomes and End Points; Mood/	Core: None
Anxiety	Supplemental – Highly Recommended: Center for Epidemiologic Studies Depression Scale (CES-D) (Acute timeframe)
	Supplemental: Beck Depression Inventory - 2 (BDI-2) (Subacute and Persistent/Chronic timeframes); Center for Epidemiologic Studies Depression Scale (CES-D) (Subacute and Persistent/Chronic timeframes); Children's Depression Inventory (Subacute and Persistent/Chronic timeframes); Generalized Anxiety Disorder 7 (GAD 7) (Subacute and Persistent/Chronic timeframes); Patient Health



	ted Concussion (SRC) CDE Highlight Summary Document
Subgroup	Recommendations
	Questionnaire (9 Item) (PHQ-9) (Subacute and Persistent/Chronic timeframes); Short Mood and Feelings Questionnaire (SMFQ) (Acute timeframe) Exploratory: Beck Depression Inventory - 2 (BDI-2) (Acute, Subacute, and Persistent Chronic timeframes); Brief Sensation Seeking Scale (BSSS) (Acute, Subacute, and Persistent Chronic timeframes); NIH Toolbox Emotional Battery(Subacute and Persistent/Chronic timeframes); Post Traumatic Stress Disorder Checklist (PCL) (Subacute and Persistent/Chronic timeframes); Screen for Child Anxiety Related Emotional Disorders (SCARED) (Subacute and Persistent/Chronic timeframes); Short Mood and Feelings Questionnaire (SMFQ) (Subacute and Persistent/Chronic timeframes); The UCLA PTSD Index for the DSM-5(Subacute and Persistent/Chronic timeframes)
Outcomes and End Points; Neurological	Core: None Supplemental – Highly Recommended: None
	Supplemental: Neurological Outcome Scale (NOS) (Subacute and Persistent/Chronic timeframes)
	Exploratory: None
Outcomes and End Points; Neuromotor Function	Core: Balance Error Scoring System (Modified) (Acute timeframe) Supplemental —Highly Recommended: Dynamic Gait Index(Persistent/Chronic timeframe); Functional Gait Assessment (Persistent/Chronic timeframe) Supplemental: Activities Specific Balance Confidence Scale (ABC-Scale)(Acute, Subacute and Persistent/Chronic timeframes); Balance Error Scoring System (Modified) (Subacute and Persistent/Chronic timeframes); Dynamic Gait Index (Subacute timeframe); Functional Gait Assessment(Subacute timeframe); NIH Toolbox Standing Balance Test (BST) (Acute and Subacute timeframes); Patient Reported Outcomes Measurement Information System (PROMIS) (Acute, Subacute and Persistent/Chronic timeframes); Walking While Talking Test (Dual Task Test) (Subacute and Persistent/Chronic timeframes); Neck Disability Index (Subacute and Persistent/Chronic timeframes) Exploratory: NIH Toolbox Motor Battery (Subacute and Persistent/Chronic timeframes); NIH Toolbox Standing Balance Test (BST) (Acute and Chronic/Persistent timeframes); BOT2 balance subset(Acute, Subacute and Persistent/Chronic timeframes);
Outcomes and End Points; Cognitive Assessments	Core: Automated Neuropsychological Assessment Metrics (ANAM)** (Acute, Subacute, and Persistent Chronic timeframes); Axon Sports Computerized Cognitive Assessment Tool (CCAT)**(Acute, Subacute, and Persistent Chronic timeframes); CNS Vital Signs** (Acute, Subacute, and Persistent Chronic timeframes); Immediate



Recommendations
Post-Concussion Assessment and Cognitive Testing (ImPACT)** (Acute, Subacute, and Persistent Chronic timeframes); Standardized Assessment of Concussion (SAC)** (Acute timeframe)
Supplemental – Highly Recommended: Children's Orientation and Amnesia Test (COAT) (Acute timeframe), Controlled Oral Word Association Test (COWAT) (Acute, Subacute, and Persistent Chronic timeframes); Hopkins Verbal Learning Test - Revised (HVLT-R) (Acute, Subacute, and Persistent Chronic timeframes); Standardized Assessment of Concussion (SAC) (Subacute timeframe); Trail Making Test (TMT) (Acute, Subacute, and Persistent Chronic timeframes); Wechsler Adult Intelligence Scale (WAIS-IV) (Acute, Subacute, and Persistent Chronic timeframes); Wechsler Intelligence Scale for Children (WISC-V) (Acute, Subacute, and Persistent Chronic timeframes)
Supplemental: Acute Concussion Evaluation Form (ACE) (Acute, Subacute, and Persistent Chronic timeframes); Behavior Rating Inventory of Executive Function (BRIEF) (Acute, Subacute, and Persistent Chronic timeframes); Brief Visuospatial Memory Test – Revised (BVMT-R) (Acute, Subacute, and Persistent Chronic timeframes); California Verbal Learning Test II *** (Persistent/Chronic timeframe); Delis-Kaplan Executive Function System (D-KEFS) (Acute, Subacute, and Persistent Chronic timeframes); Repeatable Battery for Assessment of Neuropsychological Status (RBANS) (Acute, Subacute, and Persistent Chronic timeframes); Rey Auditory Verbal Learning Test (RAVLT) (Persistent/Chronic timeframe); Stroop Test (Acute, Subacute, and Persistent Chronic timeframes); Symbol Digit Modalities Test (Acute, Subacute, and Persistent Chronic timeframes); Wide-Range Assessment of Memory and Learning-Revised (WRAML-2) (Acute, Subacute, and Persistent Chronic timeframes); Woodcock-Johnson, 3rd Edition (WJ-III); Achievement Tests (Subacute and Persistent/Chronic timeframes); Word Reading Subtest of the Wide Range Achievement Test (WRAT-4) (Acute, Subacute, and Persistent Chronic timeframes)
Exploratory: Beery-Buktenica Developmental Test of Visual-Motor Integration, 6th edition (Beery VMI) (Acute, Subacute, and Persistent Chronic timeframes); California Verbal Learning Test for Children (CVLT-C) (Acute, Subacute, and Persistent Chronic timeframes); California Verbal Learning Test II*** (Acute and Subacute timeframes); Cognitive Battery -NIH Toolbox (Acute, Subacute, and Persistent Chronic timeframes); Color-Word Interference Test (Acute, Subacute, and Persistent Chronic timeframes); Conners' Continuous Performance Test-Revised (CPT - III) (Acute, Subacute, and Persistent Chronic timeframes); Grooved Pegboard Test (Acute, Subacute, and Persistent Chronic timeframes); Rey Auditory Verbal Learning Test (RAVLT) (Acute and Subacute timelines); Test of Everyday Attention (Tea-Ch) (Acute, Subacute, and Persistent Chronic timeframes); Test of Executive Control (TEC) (Acute, Subacute, and Persistent Chronic timeframes); Test of Memory and Learning-Revised (TOMAL-2) (Acute, Subacute, and Persistent Chronic timeframes); Test of Word Reading Efficiency 2nd Edition (TOWRE-2) (Acute, Subacute, and Persistent Chronic timeframes);



Subgroup	Recommendations
Outcomes and End Points; Vestibular and Oculo Motor Function	Core: None Supplemental – Highly Recommended: Dizziness Handicap Inventory (DHI) (Subacute timeframe and Persistent/Chronic); VOMS (Brief Vestibular/Ocular Motor Screening Assessment) (Subacute timeframe)
	Supplemental: Dizziness Handicap Inventory (DHI) (Acute timeframe); Dynamic Visual Acuity Test -NIH Toolbox (Acute, Subacute and Persistent/Chronic timeframe); Tinnitus Functional Index (TFI) (Subacute and Persistent/Chronic timeframe); Tinnitus Handicap Inventory (THI) (Subacute and Persistent/Chronic timeframe); VOMS (Brief Vestibular/Ocular Motor Screening Assessment) (Persistent/Chronic timeframe); Clinical Test of Dynamic Visual Acuity (Subacute and Persistent Chronic timeframes); Computerized Test of Dynamic Visual Acuity (Subacute and Persistent/Chronic timeframes); King Devick (Acute, Subacute and Persistent/Chronic timeframe)
	Exploratory: VOMS (Brief Vestibular/Ocular Motor Screening Assessment) (<i>Acute timeframe</i>); Clinical Test of Dynamic Visual Acuity (<i>Acute timeframe</i>); Computerized Test of Dynamic Visual Acuity (<i>Acute timeframe</i>)
Outcomes and End Points; Other Symptoms	Core: None Supplemental – Highly Recommended: Brief Symptom Inventory-18 (BSI-18) (Acute timeframe)
	Supplemental: Brief Symptom Inventory-18 (BSI-18) (Subacute and Persistent/Chronic timeframe)
	Exploratory: None
Outcomes and End Points; Post- concussive/mild TBI Related Symptoms	Core: Child Sport Concussion Assessment Tool (Child-SCAT) (Acute timeframe); Health and Behavior Inventory (HBI) (Subacute and Persistent/Chronic timeframes); Post-concussion Symptom Inventory (PCSI) (Acute timeframe); Post Concussion Symptoms Scale (PCSS) (Acute, Subacute and Persistent/Chronic timeframes); The Rivermead Postconcussive Symptom Questionnaire (RPQ) (Acute, Subacute and Persistent/Chronic timeframes)
	Supplemental – Highly Recommended: Health and Behavior Inventory (HBI) (Acute timeframe)
	Supplemental: Automated Neuropsychological Assessment Metrics (ANAM) (Persistent/Chronic timeframe); Axon Sports Computerized Cognitive Assessment Tool (CCAT) (Persistent/Chronic timeframe); CNS Vital Signs (Persistent/Chronic



Subgroup	Recommendations
	timeframe); Child Sport Concussion Assessment Tool (Child-SCAT) (Acute and Persistent/Chronic timeframe); Galveston Orientation and Amnesia Test (GOAT) (Acute timeframe); Health and Behavior Inventory (HBI) (Subacute and Persistent/Chronic timeframes); Post-concussion Symptom Inventory (PCSI) (Subacute and Persistent/Chronic timeframes); Sport Concussion Assessment Tool (SCAT-3) _or 5 (Subacute and Persistent/Chronic timeframes) Exploratory: Immediate Post-Concussion Assessment and Cognitive Testing (imPACT) (Persistent/Chronic timeframe)
Outcomes and End Points; Psychological Other	Core: None Supplemental – Highly Recommended: None Supplemental: Alcohol, Smoking, and Substance Use Involvement Screening Test (ASSIST) (Pagaintant (Chronic time frame)). Alcohol Use Disorders Identification Tests
	(ASSIST) (Persistent/Chronic timeframe); Alcohol Use Disorders Identification Test: Self-Report Version (AUDIT) (Subacute and Persistent/Chronic timeframes); Substance Abuse Questions from the TBI Model Systems Database (Acute timeframe)
	Exploratory: Alcohol, Smoking, and Substance Use Involvement Screening Test (ASSIST) (<i>Subacute timeframe</i>); Kiddie Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (K-SADS-PL) (<i>Subacute and Persistent/Chronic timeframes</i>); Minnesota Multiphasic Personality Inventory – 2 – Restructured Form (MMPI-2-RF) (<i>Subacute and Persistent/Chronic timeframes</i>); NIH Toolbox Sensory Battery (<i>Subacute and Persistent/Chronic timeframes</i>); Substance Abuse Questions from the TBI Model Systems Database (<i>Subacute timeframe</i>)



Outcomes and End
Points; Quality of
Life/ Patient
Reported Outcomes

Core: None

Supplemental – Highly Recommended: Pediatric Quality of Life Inventory (PEDSQL) (*Subacute timeframe*)

Supplemental: Pediatric Quality of Life Inventory (PEDSQL) (*Acute and Persistent/Chronic timeframes*); Short Form-12 Health Survey (SF-12) (Subacute timeframe); Short Form-36 Medical Outcome Study (SF-36 v2) (*Persistent/Chronic timeframe*); Satisfaction with Life Scale (SWLS) (*Acute timeframe*)

Exploratory: NIH Toolbox Odor Identification Test (OIT) (*Persistent/Chronic timeframes*); Patient Reported Outcomes Measurement Information System (PROMIS) (*Acute, Subacute and Persistent/Chronic timeframes*); Quality of Life in Neurological Disorders (Neuro-QOL) (*Acute, Subacute and Persistent/Chronic timeframes*); Regional Taste Intensity Test - NIH Toolbox (*Persistent/Chronic timeframe*); Short Form-12 Health Survey (SF-12) (Acute timeframe); Short Form-36 Medical Outcome Study (SF-36 v2) (Subacute timeframe); TBI-QOL(*Acute, Subacute and Persistent/Chronic timeframes*)

Outcomes and End Points; Sleep

Core: None

Supplemental - Highly Recommended: None

Supplemental: Pittsburgh Sleep Quality Index(*Subacute and Persistent/Chronic timeframes*); Epworth Sleepiness Scale -Adult Scale (*Subacute and Persistent/Chronic timeframes*); Epworth Sleepiness Scale Children's Scale(*Subacute and Persistent/Chronic timeframes*)

Exploratory: Pittsburgh Sleep Quality Index(*Acute timeframe*); Epworth Sleepiness Scale Children's Scale (*Acute timeframe*); Epworth Sleepiness Scale Adult Scale (*Acute timeframe*)

Outcomes and End Points; Social Cognition

Core: None

Supplemental - Highly Recommended: None

Supplemental: None

Exploratory: Child and Adolescent Scale of Participation (CASP) (*Subacute and Persistent/Chronic timeframes*); Strengths and Difficulties Questionnaire (SDQ) (*Subacute and Persistent/Chronic timeframes*)



- *Include one or more data elements that are Core or Supplemental Highly Recommended
- ** One of the Core cognitive measures should be collected and one of the Core symptom checklists
- ***California Verbal Learning Test II Adults OR Rey Auditory Verbal Learning Test (RAVLT)