

nonizing information. Streamlining research. NeuroRehab CDE Highlight Summary

## **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. 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 <u>"Guidance for Industry: Suicidal Ideation and Behavior: Prospective</u> <u>Assessment of Occurrence in Clinical Trials</u>" 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 <u>Columbia Suicide Severity Rating Scale</u>).

Disease/Domain; Subdomain	Recommendations and List of Forms
NeuroRehab	Core and Supplemental-Highly Recommended CDEs:
	See Start-Up Resource Listing document: <u>NeuroRehab Start-Up Resource</u> Listing
	Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials
Participant	General Core: General Core
Characteristics/ Demographics	NeuroRehab Core: Infant Pediatrics Demographics
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: N/A
Assessments and	General Core: N/A
Examinations/ Autonomic	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Composite Autonomic Symptom Scale



Disease/Domain; Subdomain	Recommendations and List of Forms
Assessments and Examinations/ Comorbidities	General Core: N/A NeuroRehab Core: N/A NeuroRehab [Disease] Core: N/A NeuroRehab Supplemental-Highly Recommended: Boston Naming Test (BNT) - 30-item version; PROMIS Alcohol Use Item Banks (PROMIS Bank v1.0 - Alcohol - Negative Expectancies); PROMIS Dyspnea Item Banks (PROMIS Bank v1.0 -
Assessments and Examinations/ General and Motor	Dyspnea Functional Limitations)   General Core: N/A   NeuroRehab Core: Assessments and Examinations Demographic and Clinical Conditions
	NeuroRehab [Disease] Core: N/A NeuroRehab Supplemental-Highly Recommended: Assessments and Examinations Demographic and Clinical Conditions; Fugl-Meyer Assessment; Functional Gait Assessment
Assessments and Examinations/ Other Clinical Data	General Core: N/ANeuroRehab Core: N/ANeuroRehab Sport Related Concussion Core: Immediate Post-Concussion Assessment and Cognitive Testing (imPACT); Post Concussion Symptom ScaleNeuroRehab Supplemental-Highly Recommended: Brief Symptom Inventory-18 (BSI-18); Patient-Reported Outcomes Measurement Information System (PROMIS); Rivermead Post-Concussive Symptoms Questionnaire (RPQ)
Assessments and Examinations/ Physical/Neurological Examination	General Core: N/A NeuroRehab Core: N/A NeuroRehab Stroke Core: NIH Stroke Scale (NIHSS) NeuroRehab Supplemental-Highly Recommended: Glasgow Coma Scale (GCS)



Disease/Domain; Subdomain	Recommendations and List of Forms
Treatment/Intervention Data/ Devices	General Core: N/A
	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> Devices: Communication; Devices: Mobility and Manipulation
Outcomes and End	General Core: N/A
Points/ Academic/Intellectual	NeuroRehab Core: N/A
Functioning	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> Test of Premorbid Functioning; Wechsler Adult Intelligence Scale - Fourth Edition (WAIS-IV); Word Reading Subtest of the Wide Range Achievement Test (WRAT-4)
Outcomes and End	General Core: N/A
Points/ Activities of	NeuroRehab Core: N/A
Daily Living/Performance	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Barthel Index; Functional Independence Measure (FIM)
Outcomes and End	General Core: N/A
Points/ Amnesia/Coma	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Galveston Orientation and Amnesia Test (GOAT); JFK Coma Recovery Scale- Revised
Outcomes and End	General Core: N/A
Points/ Attention/Working Memory	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Letter-Number Sequencing Subtest; NIH Toolbox Flanker Inhibitory Control Attention Test; Wechsler Adult Intelligence Scale-Fourth Edition (WAIS-IV) - Digit Span Subtest



Disease/Domain; Subdomain	Recommendations and List of Forms
Outcomes and End Points/ Behavioral Function	General Core: N/A
	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Alcohol Use Disorders Identification Test: Self-Report Version (AUDIT); Frontal Behavioral Inventory (FBI); Frontal Systems Behavioral Scale (FrSBe)
Outcomes and End	General Core: N/A
Points/ Cognitive Activity Limitations	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> Functional Independence Measure - Cognition Subscale (Cog-FIM); PROMIS Cognitive Function Item Banks (PROMIS Bank v2.0 - Cognitive Function; PROMIS Bank v2.0 - Cognitive Function - Abilities)
Outcomes and End	General Core: N/A
Points/ Cognitive	NeuroRehab Core: N/A
Assessment	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> Brief Test of Adult Cognition by Telephone (BTACT); NIH Toolbox Cognitive Battery; Repeatable Battery for Assessment of Neuropsychological Status (RBANS)
Outcomes and End	General Core: N/A
Points/ Communication	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> Stroke and Aphasia Quality of Life-39 (SAQOL-39)
Outcomes and End Points/ Disease-Specific Health-Related Quality	General Core: N/A
	NeuroRehab Core: N/A
of Life	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: HDQLIFE; Headache Impact Test-6 (HIT-6); Myotonic Dystrophy Health Index (MDHI); Parkinson's Disease Quality of Life Scale (PDQUALIF); Spinal Cord Injury - Quality of Life (SCI-QOL); Traumatic Brain Injury - Quality of Life (TBI-QOL)



Disease/Domain; Subdomain	Recommendations and List of Forms
Outcomes and End Points/ Dysphagia	General Core: N/A
	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> Huntington's Disease Dysphasia Scale; Quality of Life in Swallowing Disorders (SWAL-QOL); Swallowing Disturbance Questionnaire (SDQ)
Outcomes and End	General Core: N/A
Points/ Emotional and	NeuroRehab Core: N/A
Cognitive Status	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> PROMIS Self-Efficacy for Managing Chronic Conditions Item Bank (PROMIS Bank v1.0 - Self-Efficacy for Managing Emotions)
Outcomes and End	General Core: N/A
Points/ Emotional	NeuroRehab Core: N/A
Impairment	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Apathy Evaluation Scale; Beck Anxiety Inventory (BAI); Beck Depression Inventory II (BDI-II)
Outcomes and End	General Core: N/A
Points/	NeuroRehab Core: N/A
Emotional/Behavioral	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: NIH Toolbox Emotional Battery; PROMIS Anxiety Item Bank (PROMIS Bank v1.0 - Anxiety); PROMIS Depression Item Bank (PROMIS Bank v1.0 - Depression)
Outcomes and End	General Core: N/A
Points/ Executive Functioning	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Five-Point Test (5-PT); Stroop Test



Disease/Domain; Subdomain	Recommendations and List of Forms
Outcomes and End Points/ Eye Hand Motor	General Core: N/A NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A NeuroRehab Supplemental-Highly Recommended: Grooved Pegboard Test
Outcomes and End Points/ Functional Outcomes	General Core: N/A NeuroRehab Core: N/A NeuroRehab [Disease] Core: N/A NeuroRehab Supplemental-Highly Recommended: 10 Meter Timed Walk; Box and Blocks Test of Manual Dexterity; Timed Up and Go (TUG)
Outcomes and End Points/ Generic Health- Related Quality of Life	General Core: N/A NeuroRehab Core: N/A NeuroRehab [Disease] Core: N/A NeuroRehab Supplemental-Highly Recommended: PROMIS-29 Profile; Short Form 36-Item Health Survey (SF-36); World Health Organization Quality of Life Assessment (WHOQOL-BREF)
Outcomes and End Points/ Global Health- Related Quality of Life Outcome	General Core: N/A NeuroRehab Core: N/A NeuroRehab [Disease] Core: N/A NeuroRehab Supplemental-Highly Recommended: PROMIS Scale v1.2 - Global Health; Quality of Life in Neurological Disorders (Neuro-QOL)
Outcomes and End Points/ Instrumental Activities of Daily Living	General Core: N/A NeuroRehab Core: N/A NeuroRehab [Disease] Core: N/A NeuroRehab Supplemental-Highly Recommended: Assessment of Life Habits (LIFE-H)



Disease/Domain; Subdomain	Recommendations and List of Forms
Outcomes and End	General Core: N/A
Points/ Language	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> Animal Naming; Controlled Oral Word Association Test (COWAT) Subtest of the Multilingual Aphasia Examination (MAE); Token Test; Western Aphasia Battery Revised
Outcomes and End	General Core: N/A
Points/ Memory	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Brief Visuospatial Memory Test Revised (BVMT-R); Hopkins Verbal Learning Test - Revised (HVLT-R); Rey Auditory Verbal Learning Test (RAVLT)
Outcomes and End	General Core: N/A
Points/ Mood/Anxiety	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> Generalized Anxiety Disorder (GAD-7); Hospital Anxiety and Depression Scale (HADS); Patient Health Questionnaire - 9 (PHQ-9) Depression Scale
Outcomes and End	General Core: N/A
Points/ Pain	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> Brief Pain Inventory (Short Form); PROMIS Pain Behavior Item Bank and Short Form (PROMIS Bank v2.0 - Pain Behavior); PROMIS Pain Interference Item Bank (PROMIS Bank v1.1 - Pain Interference)



Disease/Domain; Subdomain	Recommendations and List of Forms
Outcomes and End Points/ Participation	General Core: N/A
	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A NeuroRehab Supplemental-Highly Recommended: PROMIS Ability to Participate Item Bank and Short Forms (PROMIS Item Bank v2.0 - Ability to Participate in Social Roles and Activities; PROMIS Short Form v2.0 - Ability to Participate in Social Roles and Activities 4a; PROMIS Short Form v2.0 - Ability to Participate in Social Roles and Activities 6a; PROMIS Short Form v2.0 - Ability to Participate in Social Roles and Activities 6a; PROMIS Short Form v2.0 - Ability to Participate in Social Roles and Activities 8a); PROMIS v2.0 - Satisfaction with Social Roles and Activities
Outcomes and End	General Core: N/A
Points/ Pediatric	<b>NeuroRehab Core:</b> Pediatric Quality of Life Inventory (PedsQL); Strengths and Difficulties Questionnaire (SDQ), combined Full and Followup versions
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: N/A
Outcomes and End	General Core: N/A
Points/ Performance Validity Tests	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Medical Symptom Validity Test (MSVT); Test of Memory Malingering (TOMM); Victoria Symptom Validity Test (VSVT)
Outcomes and End	General Core: N/A
Points/ Physical	NeuroRehab Core: N/A
Function	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> 2 Minute Walk Test; 6 Minute Walk Test; Borg Rating of Perceived Exertion (RPE) Scale
Outcomes and End Points/ Processing Speed	General Core: N/A
	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> Processing Speed Index of the Wechsler Adult Intelligence Scale-Fourth Edition (WAIS-IV); Symbol Digit Modalities Test; Trail Making Test



Disease/Domain; Subdomain	Recommendations and List of Forms
Outcomes and End Points/ Psychiatric and Psychological Functions	General Core: N/A
	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Apathy Scale (AS); Columbia - Suicide Severity Rating Scale (C-SSRS); Impact of Event Scale (IES)
Outcomes and End	General Core: N/A
Points/ Psychiatric and	NeuroRehab Core: N/A
Psychological Status	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> Alcohol, Smoking, and Substance Use Involvement Screening Test (ASSIST); PTSD Checklist for DSM-5 (PCL-5); Structured Clinical Interview for DSM-5 Axis I Disorders Research Version (SCID-5-RV)
Outcomes and End	General Core: N/A
Points/ Psychological	NeuroRehab Core: N/A
Status	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> Center for Epidemiologic Studies-Depression Scale (CES-D); Hamilton Anxiety Rating Scale (HAM-A); Hamilton Depression Rating Scale (HDRS)
Outcomes and End	General Core: N/A
Points/ Screening	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	<b>NeuroRehab Supplemental-Highly Recommended:</b> Mini-Mental State Examination (MMSE); Montreal Cognitive Assessment (MoCA); Telephone Interview for Cognitive Status (TICS)
Outcomes and End Points/ Sleep	General Core: N/A
	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Neuro-QOL Adult Bank - Sleep Disturbance; PROMIS Sleep Item Banks (PROMIS Bank v1.0 - Sleep Disturbance; PROMIS Bank v1.0 - Sleep-Related Impairment)



Disease/Domain; Subdomain	Recommendations and List of Forms
Outcomes and End Points/ Speech	General Core: N/A NeuroRehab Core: N/A NeuroRehab [Disease] Core: N/A NeuroRehab Supplemental-Highly Recommended: Acoustic Analysis of Speech; Voice Handicap Index (VHI); Assessment of Intelligibility of Dysarthric Speech (AIDS)
Outcome and End Points/ Trunk Control/Balance	General Core: N/A NeuroRehab Core: N/A NeuroRehab [Disease] Core: N/A NeuroRehab Supplemental-Highly Recommended: Activities Specific Balance Confidence Scale (ABC-Scale); Berg Balance Scale (BBS); Mini- Balance Evaluation Systems Test (Mini-BESTest)
Outcomes and End Points/ Visual	General Core: N/A NeuroRehab Core: N/A NeuroRehab [Disease] Core: N/A NeuroRehab Supplemental-Highly Recommended: Judgment of Line Orientation (Benton JLO); Rey-Osterrieth Complex Figure Test (ROCF)