

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 Characteristics/ Demographics	General Core: General Core NeuroRehab Core: Infant Pediatrics Demographics NeuroRehab [Disease] Core: N/A
Assessments and Examinations/ Autonomic	NeuroRehab Supplemental-Highly Recommended: N/A General Core: N/A NeuroRehab Core: N/A NeuroRehab [Disease] Core: N/A NeuroRehab Supplemental-Highly Recommended: Composite Autonomic



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



Disease/Domain; Subdomain	Recommendations and List of Forms
Outcomes and End Points/ Academic/Intellectual Functioning	General Core: N/A NeuroRehab Core: N/A NeuroRehab [Disease] Core: N/A NeuroRehab Supplemental-Highly Recommended: 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 Points/ Activities of Daily Living/Performance	General Core: N/A NeuroRehab Core: N/A NeuroRehab [Disease] Core: N/A NeuroRehab Supplemental-Highly Recommended: Barthel Index; Functional Independence Measure (FIM)
Outcomes and End Points/ Amnesia/Coma	General Core: N/A 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 Points/ Attention/Working Memory	General Core: N/A 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
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)



Disease/Domain; Subdomain	Recommendations and List of Forms
Outcomes and End Points/ Cognitive	General Core: N/A
	NeuroRehab Core: N/A
Activity Limitations	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Functional Independence Measure - Cognition Subscale (Cog-FIM); PROMIS Item Bank v2.0 - Cognitive Function; PROMIS Item Bank v2.0 - Cognitive Function Abilities Subset
Outcomes and End	General Core: N/A
Points/ Cognitive Assessment	NeuroRehab Core: N/A
Assessment	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: 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
	NeuroRehab Supplemental-Highly Recommended: Stroke and Aphasia Quality of Life-39 (SAQOL-39)
Outcomes and End	General Core: N/A
Points/ Disease-Specific Health-Related Quality	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)
Outcomes and End	General Core: N/A
Points/ Dysphagia	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Huntington's Disease Dysphasia Scale; Quality of Life in Swallowing Disorders (SWAL-QOL); Swallowing Disturbance Questionnaire (SDQ)



Disease/Domain; Subdomain	Recommendations and List of Forms
Outcomes and End Points/ Emotional and	General Core: N/A
	NeuroRehab Core: N/A
Cognitive Status	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: PROMIS Item 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 Item Bank v1.0 - Emotional Distress - Anxiety; PROMIS Item Bank v1.0 - Emotional Distress - Depression (Calibrated Items)
Outcomes and End	General Core: N/A
Points/ Executive	NeuroRehab Core: N/A
Functioning	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Five-Point Test (5-PT); Stroop Test
Outcomes and End	General Core: N/A
Points/ Eye Hand	NeuroRehab Core: N/A
Motor	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Grooved Pegboard Test
Outcomes and End	General Core: N/A
Points/ Functional Outcomes	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)



Disease/Domain; Subdomain	Recommendations and List of Forms
Outcomes and End Points/ Generic Health- Related Quality of Life	General Core: N/A
	NeuroRehab Core: N/A
helatea Quanty of Life	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	General Core: N/A
Points/ Global Health- Related Quality of Life	NeuroRehab Core: N/A
Outcome	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: PROMIS Item Bank v1.2 - Global Health; Quality of Life in Neurological Disorders (Neuro-QOL)
Outcomes and End	General Core: N/A
Points/ Instrumental Activities of Daily Living	NeuroRehab Core: N/A
Activities of Daily Living	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Assessment of Life Habits (LIFE-H)
Outcomes and End	General Core: N/A
Points/ Language	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: 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)



Disease/Domain; Subdomain	Recommendations and List of Forms
Outcomes and End Points/ Mood/Anxiety	General Core: N/A
	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: 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
	NeuroRehab Supplemental-Highly Recommended: Brief Pain Inventory (Short Form); PROMIS Item Bank v1.1 - Pain Interference; PROMIS Item Bank v2.0 - Pain Behavior
Outcomes and End	General Core: N/A
Points/ Participation	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: PROMIS v2.0 - Ability to Participate in Social Roles and Activities; PROMIS v2.0 - Satisfaction with Social Roles and Activities
Outcomes and End	General Core: N/A
Points/ Pediatric	NeuroRehab Core: 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)



Disease/Domain; Subdomain	Recommendations and List of Forms
Outcomes and End Points/ Physical Function	General Core: N/A
	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: 2 Minute Walk Test; 6 Minute Walk Test; Borg Rating of Perceived Exertion (RPE) Scale
Outcomes and End	General Core: N/A
Points/ Processing	NeuroRehab Core: N/A
Speed	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Processing Speed Index of the Wechsler Adult Intelligence Scale-Fourth Edition (WAIS-IV); Symbol Digit Modalities Test; Trail Making Test
Outcomes and End	General Core: N/A
Points/ Psychiatric and	NeuroRehab Core: N/A
Psychological Functions	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
	NeuroRehab Supplemental-Highly Recommended: 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
	NeuroRehab Supplemental-Highly Recommended: Center for Epidemiologic Studies-Depression Scale (CES-D); Hamilton Anxiety Rating Scale (HAM-A); Hamilton Depression Rating Scale (HDRS)



Disease/Domain; Subdomain	Recommendations and List of Forms
Outcomes and End	General Core: N/A
Points/ Screening	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Mini-Mental State Examination (MMSE); Montreal Cognitive Assessment (MoCA); Telephone Interview for Cognitive Status (TICS)
Outcomes and End	General Core: N/A
Points/ Sleep	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Neuro-QOL Adult Bank - Sleep Disturbance; PROMIS Item Bank v1.0 - Sleep Disturbance; PROMIS Item Bank v1.0 - Sleep Related Impairment
Outcomes and End	General Core: N/A
Points/ Speech	NeuroRehab Core: N/A
	NeuroRehab [Disease] Core: N/A
	NeuroRehab Supplemental-Highly Recommended: Acoustic Analysis of Speech; Voice Handicap Index (VHI)
Outcome and End	General Core: N/A
Points/ Trunk	NeuroRehab Core: N/A
Control/Balance	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	General Core: N/A
Points/ Visual	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)