



**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 ["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 <http://www.cssrs.columbia.edu>)

<b>Disease/Domain</b>	<b>Recommendations</b>
<b>Epilepsy</b>	<p><b>These instruments and elements are recommended for use in Epilepsy studies:</b></p> <p><b>Core elements:</b></p> <p>See Start-Up Resources Listing document (<a href="#">Epilepsy Start-Up Resource Listing</a>)</p> <p><b>Supplemental – Highly Recommended instruments:</b></p> <p><a href="#">American National Adult Reading Test (AmNART)</a>, <a href="#">Montreal Cognitive Assessment (MoCA)</a>, <a href="#">Hopkins Verbal Learning Test (HVLT)</a>, <a href="#">Boston Naming Test (BNT)</a>, <a href="#">Controlled Oral Word Association (COWAT)</a>, <a href="#">Continuous Performance Test-III</a>, <a href="#">Beck Depression Inventory-II</a>, <a href="#">Seizure Diary</a></p>
<b>Participant / Subject Characteristics; Demographics</b>	<p><b>Core:</b> Demographics, General Core</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Demographics</p>
<b>Participant / Subject Characteristics; Social Status</b>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> Social Status</p> <p><b>Supplemental:</b> Social Status</p>
<b>Disease / Injury Related Events; Classification</b>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> Classification of Seizures, Classification of Etiology, Syndromes by Age of Onset</p> <p><b>Supplemental:</b> Classification of Seizures, Classification of Etiology, Syndromes by Age of Onset</p>



**Epilepsy CDE Highlight Summary Document**

Disease/Domain	Recommendations
Assessments and Examinations / Physical; Neurological Exam	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Physical Exam, Neurological Exam, PROMIS</p>
Assessments and Examinations; Vital Signs and Other Body Measures	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Vital Signs</p>
Assessments and Examinations; Laboratory Tests and Biospecimens / Biomarkers	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> NINDS Repository Epilepsy Data Elements</p>
Assessments and Examinations; Imaging Diagnostics	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Acquisition and outcome data (fMRI, SPECT, MRI, MEG, MRI for Registration of MEG, PET)</p>
Assessments and Examinations; Non-Imaging Diagnostics	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Scalp Electroencephalography (EEG), Short Scalp Electroencephalography (EEG)</p>
Treatment / Intervention Data; Drugs	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> AED Plasma Concentration, AED Resistance Log, Anti Epileptic Drug (AED) Log, Non Anti Epileptic Medication Log</p>
Treatment / Intervention Data; Devices	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Device Revision/Replacement Log, Devices Log, Implanted Devices Log</p>
Treatment / Intervention Data; Surgeries and Other Procedures	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Surgery and Pathology</p>



Disease/Domain	Recommendations
<p><b>Safety Data; Adverse Events</b></p>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Adverse Event Tracking Log, Hague Side Effects Scale, VA Toxicity Scale</p>
<p><b>Outcomes and Endpoints; Assessing Comorbidities</b></p>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> American National Reading Test (AmNART), Montreal Cognitive Assessment (MoCA), Hopkins Verbal Learning Test-Revised (HVLT-R), Boston Naming Test (BNT), Controlled Oral Word Association Test (COWAT), Continuous Performance Test-II, Beck Depression Inventory-II</p> <p><b>Supplemental:</b> Adult ADHD Self-Report Scale (ASRS), Checklist for Autism in Toddlers (CHAT), Headache Screening Survey, Longitudinal Interval Follow-Up Evaluation (DSM-IV Version (LIFE DSM-IV), Patient Health Questionnaire-9 (PHQ-9), Generalized Anxiety disorder (GAD-7), ADHD Comprehensive Teachers Rating Scale (ACTeRS), Adolescent Symptom Inventory (ASI), Beck Anxiety Inventory (BAI), Brief Psychiatric Rating Scale (BPRS), Child Behavior Checklist (CBCL), Child Depression Inventory (CDI), Child Health Questionnaire (CHQ), Child Symptom Inventory (CSI), Childhood Autism Rating Scale (CARS), Conners Teacher and Parent Rating Scale (CRS-R), Davidson Trauma Scale (DTS), Headache Diagnosis Questionnaire, Migraine Headaches Questionnaire 21 – Item, Mini International Neuropsychiatric Interview (MINI), Modified Checklist for Autism in Toddlers (M-CHAT), National Institute of Mental Health Diagnostic Interview Schedule for Children (NIMH-DISC), Neurological Disorders Depression Inventory in Epilepsy (NDDI-E), Psychiatric Diagnostic Screening Questionnaire (PDSQ), Social Communication Questionnaire (SCQ), World Health Organization (WHO) Composite International Diagnostic Interview (WMH-CIDI) and The NIH Toolbox</p>



<b>Disease/Domain</b>	<b>Recommendations</b>
<p><b>Outcomes and Endpoints; Neuropsychological Testing</b></p>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Neuropsychological Testing Background Information, Brief Visuospatial Memory Test Revised (BVMTR), California Verbal learning Test-Children’s Version (CVLT-C), California Verbal Learning Test-2 (CVLT-2), Clinical Evaluation of Language Fundamentals – 4<sup>th</sup> Ed. (CELF-4), Delis Kaplan Executive Functioning System (DKEFS) – Trail Making Tests, Grooved Pegboard Test, Mullen Scales of Early Learning (MSEL), Peabody Picture Vocabulary Test 4<sup>th</sup> Edition (PPVT-4), Rey Auditory Verbal Learning Test (RAVLT), Wechsler Abbreviated Scale of Intelligence (WASI), Wisconsin Card Sorting Test (WCST), Rey-Osterrieth Complex Figure (ROCF) Copy and Delay, Bayley Scales of Infant Development (Bayley III, BSID), Adaptive Behavior Assessment Scale (ABAS-II), Behavior Rating Inventory of Executive Function (BRIEF), Conners Kiddie Continuous Performance Test (K-CPT), Purdue Pegboard, Scales of Independent Behavior-Revised (SIB-R), Test of Variable Attention (TOVA), Vineland Adaptive Behavior Scales, second edition (Vineland-II), Wechsler Preschool and Primary Scale of Intelligence (WPPSI-III)</p>
<p><b>Outcomes and Endpoints; Patient Reported Outcomes</b></p>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> Seizure Diary</p> <p><b>Supplemental:</b> None</p>
<p><b>Outcomes and Endpoints; Quality of life</b></p>	<p><b>Core:</b> None</p> <p><b>Supplemental – Highly Recommended:</b> None</p> <p><b>Supplemental:</b> Healthy Days Core Module (CDC HRQOL-4), Pediatric Quality of Life Inventory (PEDSQL), Quality of Life in Epilepsy Inventory for Adolescents (QOLIE-48), Quality of Life in Epilepsy Inventory -10 (QOLIE-10), Quality of Life in Epilepsy Inventory-31 (QOLIE-31), Quality of Life in Epilepsy Inventory-89 (QOLIE-89), The DISABKIDS Chronic Generic Module (DCGM-37), Quality of Life in Neurological Disorders (Neuro-QoI)</p>