

Epilepsy CDE Revision History Document

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November 2023 Revisions

The Magnetic Resonance Imaging (MRI) CRF and data dictionary was updated.

33 CDEs were added to the CRF classified as Supplemental

C18718 Imaging scanner strength value other text
C59601 Imaging specific abnormality contrast agent use indicator
C13977 Imaging abnormality cortical anatomic site
C59591 Imaging normality status
C59602 Imaging hippocampal sclerosis type
C13978 Imaging abnormality subcortical anatomic site
C59592 Imaging abnormality description type
C59603 Imaging hippocampal sclerosis type other text
C13979 Imaging abnormality feature type
C59593 Imaging abnormality description type other text
C59604 Imaging malformation cortical development type other text
C13980 Imaging specific abnormality impression type
C59594 Imaging abnormality cortical identification code
C59605 Imaging vascular disorder type other text
C14040 Imaging vascular disorder type
C59595 Imaging abnormality cortical contrast agent use indicator
C59606 Imaging inflammatory infection type other text
C02494 Imaging study date and time
C14041 Imaging neoplasm status type
C59596 Imaging abnormality subcortical side type
C02495 Imaging scanner strength value
C14042 Imaging inflammatory infection type
C59597 Imaging abnormality subcortical identification code
C10570 Imaging contrast agent used indicator
C14043 Imaging atrophy tissue loss type
C59598 Imaging abnormality subcortical contrast agent used indicator
C13973 Imaging epilepsy-specific protocol indicator
C18525 Imaging abnormality cortical side type
C59599 Imaging abnormality feature type identification code
C13975 Imaging abnormality count
C18527 Imaging malformation of cortical development type
C59600 Imaging specific abnormality laterality type
C13976 Imaging abnormality distribution type

The following revisions were made to the Epilepsy Highlight Summary Document:

Revised Domain name: '**Participant / Subject Characteristics**' to '**Participant Characteristics**'

- Reordered Assessments and Examinations; Subdomains into the order as they appear on the Epilepsy data standards webpage.
- **Assessments and Examinations/ Imaging Diagnostics**

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- Revised Domain; Subdomain name: 'Assessments and Examinations/ Imaging Diagnostics' to: 'Assessments and Examinations; Imaging Diagnostics'
- Revised 'Supplemental' listings from 'Acquisition and outcome data (fMRI, SPECT, MRI, MEG, MRI for Registration of MEG, PET)' to: 'Magnetic Resonance Imaging (MRI), Functional Magnetic Resonance Imaging (fMRI), Ictal Single-photon Emission Computed Tomography (SPECT) Localization, Magnetoencephalography (MEG) Acquisition, MRI for Registration of MEG, Positron Emission Tomography (PET)'
- **Assessments and Examinations/Physical; Neurological Exam**
 - Revised Domain; Subdomain name: 'Assessments and Examinations/Physical; Neurological Exam' to: 'Assessments and Examinations; Physical/Neurological Examination'
- **Outcomes and Endpoints; Assessing Comorbidities**
 - Revised 'Continuous Performance Test-II' to: 'Conner's Continuous Performance Test-III'
 - Removed 'Headache Screening Survey'
 - Revised 'Patient Health Questionnaire-9 (PHQ-9)' to: 'Patient Health Questionnaire - 9 (PHQ-9) Depression Scale'
 - Revised 'Conners Teacher and Parent Rating Scale (CRS-R)' to: Conners' (Teacher and Parent) Rating Scale (CRS-R)'
 - Added 'Post-Traumatic Epilepsy Screening Form'
- **Outcomes and Endpoints; Neuropsychological Testing**
 - Revised 'California Verbal Learning Test-2 (CVLT-2)' to: 'California Verbal Learning Test - Second Edition (CVLT-II)'
 - Revised 'Clinical Evaluation of Language Fundamentals – 4th (CELF-4)' to: 'Clinical Evaluation of Language Fundamentals - Fifth Edition (CELF-5)'
 - Revised 'Conners Kiddie Continuous Performance Test (K-CPT)' to: 'Conners Kiddie Continuous Performance Test 2 (K-CPT 2)'
 - Revised 'Delis Kaplan Executive Functioning System (DKEFS) – Trail Making Tests' to: 'Delis Kaplan Executive Functioning System (DKEFS)'
 - Added 'Processing Speed Index of the Wechsler Adult Intelligence Scale-Fourth Edition (WAIS-IV)'

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- Added: 'Processing Speed Index of the Wechsler Intelligence Scale for Children-IV/Wechsler Preschool and Primary Scale of Intelligence (WISC-IV/WPPSI-III)'
- **Outcomes and Endpoints; Quality of Life**
 - Revised Domain; Subdomain name: 'Outcomes and Endpoints; Quality of life' to: 'Outcomes and Endpoints; Quality of Life/Patient Reported Outcomes'

August 2022 Revisions

The Epilepsy Surgery & Pathology CRF was updated.

168 New CDEs were added to the CRF classified as Supplemental – Highly Recommended:

C59368	Suspected pathology type
C59369	Suspected pathology type other text
C59370	Surgery diagnostic electrode type other text
C59371	Surgery diagnostic electrode depth anatomic site
C59372	Surgery diagnostic electrode depth anatomic site other text
C59373	Surgery diagnostic electrode depth hippocampus laterality type
C59374	Surgery diagnostic electrode depth frontal laterality type
C59375	Surgery diagnostic electrode depth temporal laterality type
C59376	Surgery diagnostic electrode depth parietal laterality type
C59377	Surgery diagnostic electrode depth occipital laterality type
C59378	Surgery diagnostic electrode depth insula laterality type
C59379	Surgery diagnostic electrode depth amygdala laterality type
C59380	Surgery diagnostic electrode depth other laterality type
C59381	Surgery diagnostic electrode subdural anatomic site
C59382	Surgery diagnostic electrode subdural anatomic site other text
C59383	Surgery diagnostic electrode subdural hippocampus laterality type
C59384	Surgery diagnostic electrode subdural frontal laterality type
C59385	Surgery diagnostic electrode subdural temporal laterality type
C59386	Surgery diagnostic electrode subdural parietal laterality type
C59387	Surgery diagnostic electrode subdural occipital laterality type
C59388	Surgery diagnostic electrode subdural insula laterality type
C59389	Surgery diagnostic electrode subdural amygdala laterality type
C59390	Surgery diagnostic electrode subdural other laterality type
C59391	Surgery diagnostic electrode epidural anatomic site
C59393	Surgery diagnostic electrode epidural anatomic site other text
C59394	Surgery diagnostic electrode epidural hippocampus laterality type
C59395	Surgery diagnostic electrode epidural frontal laterality type
C59410	Surgery diagnostic electrode epidural temporal laterality type
C59411	Surgery diagnostic electrode epidural parietal laterality type
C59412	Surgery diagnostic electrode epidural occipital laterality type

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C59414	Surgery diagnostic electrode epidural insula laterality type
C59416	Surgery diagnostic electrode epidural amygdala laterality type
C59420	Surgery diagnostic electrode epidural other laterality type
C59426	Surgery diagnostic electrode foramen ovale anatomic site
C59427	Surgery diagnostic electrode foramen ovale anatomic site other text
C59429	Surgery diagnostic electrode foramen ovale hippocampus laterality type
C59430	Surgery diagnostic electrode foramen ovale frontal laterality type
C59431	Surgery diagnostic electrode foramen ovale temporal laterality type
C59433	Surgery diagnostic electrode foramen ovale parietal laterality type
C59435	Surgery diagnostic electrode foramen ovale occipital laterality type
C59438	Surgery diagnostic electrode foramen ovale insula laterality type
C59439	Surgery diagnostic electrode foramen ovale amygdala laterality type
C59440	Surgery diagnostic electrode foramen ovale other laterality type
C59456	Surgery diagnostic electrode interhemispheric anatomic site
C59457	Surgery diagnostic electrode interhemispheric anatomic site other text
C59458	Surgery diagnostic electrode other location anatomic site
C59459	Surgery diagnostic electrode other location anatomic site other text
C59460	Surgery diagnostic electrode other type hippocampus laterality type
C59461	Surgery diagnostic electrode other type frontal laterality type
C59462	Surgery diagnostic electrode other type temporal laterality type
C59463	Surgery diagnostic electrode other type parietal laterality type
C59464	Surgery diagnostic electrode other type occipital laterality type
C59465	Surgery diagnostic electrode other type insula laterality type
C59466	Surgery diagnostic electrode other type amygdala laterality type
C59467	Surgery diagnostic electrode other type other laterality type
C59468	Surgery anterior temporal lobectomy laterality type
C59469	Surgery anterior temporal lobectomy resection size estimate type
C59470	Surgery anterior temporal lobectomy plus extended resection lateral temporal laterality type
C59471	Surgery anterior temporal lobectomy plus extended resection occipital laterality type
C59472	Surgery anterior temporal lobectomy plus extended resection parietal laterality type
C59473	Surgery anterior temporal lobectomy plus extended resection orbitofrontal laterality type
C59474	Surgery anterior temporal lobectomy plus extended resection dorsolateral frontal laterality type
C59475	Surgery anterior temporal lobectomy plus extended resection medial frontal laterality type
C59476	Surgery anterior temporal lobectomy plus extended resection central cortex laterality type
C59477	Surgery anterior temporal lobectomy plus resection size estimate type
C59478	Surgery amygdalohippocampectomy laterality type
C59479	Surgery amygdalohippocampectomy approach anatomic site other text
C59480	Surgery amygdalohippocampectomy resection size estimate type
C59481	Surgery lesionectomy suspect lesion anatomic site other text

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C59482	Surgery lesionectomy suspect lesion lateral temporal laterality type
C59483	Surgery lesionectomy suspect lesion medial temporal laterality type
C59484	Surgery lesionectomy suspect lesion occipital laterality type
C59485	Surgery lesionectomy suspected lesion parietal laterality type
C59486	Surgery lesionectomy suspect lesion hypothalamus laterality type
C59487	Surgery lesionectomy suspect lesion orbitofrontal laterality type
C59488	Surgery lesionectomy suspect lesion dorsolateral frontal laterality type
C59489	Surgery lesionectomy suspect lesion medial frontal laterality type
C59490	Surgery lesionectomy suspect lesion central cortex laterality type
C59491	Surgery lesionectomy suspect lesion insula laterality type
C59492	Surgery lesionectomy suspect lesion multifocal laterality type
C59493	Surgery lesionectomy suspect lesion other anatomic site laterality type
C59494	Surgery lesionectomy resection size estimate type
C59495	Surgery lesionectomy plus resection extent type
C59496	Surgery lesionectomy plus resection size estimate type
C59497	Surgery neocortical resection anatomic site
C59498	Surgery neocortical resection lateral temporal laterality type
C59499	Surgery neocortical resection occipital laterality type
C59500	Surgery neocortical resection parietal laterality type
C59501	Surgery neocortical resection orbitofrontal laterality type
C59502	Surgery neocortical resection dorsolateral frontal laterality type
C59503	Surgery neocortical resection medial frontal laterality type
C59504	Surgery neocortical resection central cortex laterality type
C59505	Surgery neocortical resection insula laterality type
C59506	Surgery neocortical resection size estimate type
C59507	Surgery neocortical resection largest anterior-posterior extent estimated value
C59508	Surgery neocortical resection largest lateral extent estimated value
C59509	Surgery neocortical resection largest depth estimated value
C59510	Surgery neocortical resection tissue estimated volume value
C59511	Surgery multi-lobar temporal lobe resection indicator
C59512	Surgery multi-lobar temporal lobe resection laterality type
C59513	Surgery multi-lobar temporal lobe resection percent estimate remove type
C59514	Surgery multi-lobar temporal lobe resection temporal percentage estimate remove range
C59515	Surgery multi-lobar occipital lobe resection indicator
C59516	Surgery multi-lobar occipital lobe resection laterality type
C59517	Surgery multi-lobar occipital lobe resection estimate type
C59518	Surgery multi-lobar percent estimate occipital lobe resection remove range
C59519	Surgery multi-lobar parietal lobe resection indicator
C59520	Surgery multi-lobar parietal lobe resection laterality type
C59521	Surgery multi-lobar percent estimate parietal lobe resection remove type
C59522	Surgery multi-lobar percentage estimate parietal lobe resection remove range

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C59523	Surgery multi-lobar frontal lobe resection indicator
C59524	Surgery multi-lobar frontal lobe resection laterality type
C59525	Surgery multi-lobar percent estimate frontal lobe resection remove type
C59526	Surgery multi-lobar percent estimate frontal lobe resection remove range
C59527	Surgery multi-lobar insula resection indicator
C59528	Surgery multi-lobar insula resection laterality type
C59529	Surgery multi-lobar percent estimate insula resection remove type
C59530	Surgery multi-lobar percent estimate insula resection remove range
C59531	Surgery hemispherectomy laterality type
C59532	Surgery vagus nerve stimulation laterality type
C59533	Surgery corpus callosotomy disconnection tissue type
C59534	Surgery multiple subpial transection lateral temporal laterality type
C59535	Surgery multiple subpial transection medial temporal laterality type
C59536	Surgery multiple subpial transection occipital laterality type
C59537	Surgery multiple subpial transection parietal laterality type
C59538	Surgery multiple subpial transection orbitofrontal laterality type
C59539	Surgery multiple subpial transection dorsolateral frontal laterality type
C59540	Surgery multiple subpial transection medial frontal laterality type
C59541	Surgery multiple subpial transection central cortex laterality type
C59542	Surgery multiple subpial transection estimate size type
C59543	Surgery stereotactic lesion present MRI indicator
C59544	Surgery stereotactic lesion method type
C59545	Surgery stereotactic lesion perform anatomic site
C59546	Surgery stereotactic lesion medial temporal laterality type
C59547	Surgery stereotactic lesion lateral temporal laterality type
C59548	Surgery stereotactic lesion occipital laterality type
C59549	Surgery stereotactic lesion parietal laterality type
C59550	Surgery stereotactic lesion orbitofrontal laterality type
C59551	Surgery stereotactic lesion dorsolateral frontal laterality type
C59552	Surgery stereotactic lesion medial frontal laterality type
C59553	Surgery stereotactic lesion central cortex laterality type
C59554	Surgery stereotactic lesion insula laterality type
C59555	Surgery stereotactic lesion periventricular laterality type
C59556	Therapeutic brain stimulation procedure type
C59557	Therapeutic brain stimulation procedure cortical anatomic site
C59558	Therapeutic brain stimulation procedure cortical hippocampus laterality type
C59559	Therapeutic brain stimulation procedure cortical lateral temporal laterality type
C59560	Therapeutic brain stimulation cortical occipital procedure laterality type
C59561	Therapeutic brain stimulation cortical parietal procedure laterality type
C59562	Therapeutic brain stimulation cortical orbitofrontal laterality procedure type
C59563	Therapeutic brain stimulation cortical dorsolateral frontal procedure laterality type

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C59564	Therapeutic brain stimulation cortical medial frontal procedure laterality type
C59565	Therapeutic brain stimulation cortical central cortex procedure laterality type
C59566	Therapeutic brain stimulation cortical insula procedure laterality type
C59567	Therapeutic brain stimulation subcortical procedure anatomic site
C59568	Therapeutic brain stimulation subcortical anterior thalamus procedure laterality type
C59569	Therapeutic brain stimulation subcortical centromedian thalamus procedure laterality type
C59570	Therapeutic brain stimulation subcortical cerebellum procedure laterality type
C59571	Therapeutic brain stimulation subcortical subthalamic nucleus procedure laterality type
C59572	Therapeutic brain stimulation subcortical brainstem laterality procedure type
C59573	Therapeutic brain stimulation pulse polarity type other text
C59574	Pathology lesionectomy tumor astrocytoma grade
C59575	Pathology lesionectomy tumor mixed glioma grade
C59576	Pathology lesionectomy tumor oligodendroglioma grade
C59577	Pathology lesionectomy tumor other low grade developmental grade
C59578	Surgery post-operative neurologic visual field deficit type
C59579	Surgery post-operative cranial nerve deficit complication text
C59580	Surgery post-operative medical complication wound infection type

27 CDEs were removed from the CRF:

C02411	Laterality type
C14298	Surgery diagnostic anatomic site
C14315	Surgery lesionectomy suspected lesion type
C14315	Surgery lesionectomy suspected lesion type
C14323	Surgery lesionectomy plus extended resection anatomic site
C14324	Surgery extratemporal resection largest anterior-posterior extent estimated value
C14325	Surgery extratemporal resection largest lateral extent estimated value
C14326	Surgery extratemporal resection largest depth estimated value
C14327	Surgery extratemporal resection tissue estimated volume value
C14328	Surgery extratemporal resection anatomic site
C14331	Surgery multi-lobar resection lobe indicator
C14332	Surgery multi-lobar resection lobe percentage remove range
C14336	Surgery vagus nerve stimulator implanted indicator
C14337	Surgery corpus callosotomy anatomic site
C14343	Surgery radiosurgery lobe location text
C14344	Surgery radiosurgery lesion indicator
C14346	Surgery radiosurgery treatment volume value
C14348	Surgery radiosurgery treatment session count
C17642	Surgery radiosurgery lesion text
C17644	Therapeutic brain stimulation postoperative MRI Tesla value
C18583	Pathology lesionectomy tumor finding grade
C18765	Surgical or therapeutic procedure other text

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C18915	Surgery lesionectomy suspected lesion other text
C18916	Surgery lesionectomy suspected lesion anatomic other text
C18919	Surgery corpus callosotomy anatomic other text
C18920	Surgery corpus callosotomy resection extent other text
C21668	ICD-10-CM code
C21669	Surgical therapeutic procedure ICD-10-CM other text

89 CDEs were upgraded in classification from Supplemental to Supplemental – Highly Recommended:

C05106 Surgical or therapeutic procedure start date and time

C05108 Surgical or therapeutic procedure type

C08039 Electrode brain count

C14297 Surgery diagnostic electrode type

C14299 Surgery anterior temporal lobectomy superior temporal gyrus resection estimated length value

C14300 Surgery anterior temporal lobectomy middle temporal gyrus resection estimated length value

C14301 Surgery anterior temporal lobectomy inferior temporal gyrus resection estimated length value

C14302 Surgery anterior temporal lobectomy parahippocampal gyrus resection estimated length value

C14303 Surgery anterior temporal lobectomy amygdala resection estimated percentage value

C14304 Surgery anterior temporal lobectomy hippocampus resection estimated length value

C14305 Surgery anterior temporal lobectomy plus adjacent resection indicator

C14306 Surgery anterior temporal lobectomy plus largest anterior-posterior extent of resection
estimated value

C14307 Surgery anterior temporal lobectomy plus largest lateral extent of resection estimated value

C14308 Surgery anterior temporal lobectomy plus largest depth of resection estimated value

C14309 Surgery anterior temporal lobectomy plus resected tissue estimated volume value

C14310 Surgery anterior temporal lobectomy plus extended resection anatomic site

C14311 Surgery amygdalohippocampectomy parahippocampal estimated length value

C14312 Surgery amygdalohippocampectomy amygdala estimated percentage value

C14313 Surgery amygdalohippocampectomy hippocampus estimated length value

C14314 Surgery amygdalohippocampectomy approach anatomic site

C14316 Surgery lesionectomy suspect lesion anatomic site

C14317 Surgery lesionectomy resection extent type

C14318 Surgery lesionectomy plus adjacent resection indicator

C14319 Surgery lesionectomy plus largest anterior-posterior extent of resection estimated value

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C14320 Surgery lesionectomy plus largest lateral extent of resection estimated value

C14321 Surgery lesionectomy plus largest depth of resection estimated value

C14322 Surgery lesionectomy plus resected tissue estimated volume value

C14329 Surgery multi-lobar resection lesion indicator

C14330 Surgery multi-lobar resection lobe anatomic site

C14335 Surgery hemispherectomy type

C14338 Surgery corpus callosotomy disconnection extent type

C14339 Surgery multiple subpial transection largest anterior-posterior dimension estimated value

C14340 Surgery multiple subpial transection largest lateral dimension estimated value

C14341 Surgery multiple subpial transection anatomic site

C14342 Surgery multiple subpial transection with resection indicator

C14347 Surgery radiosurgery marginal dose value

C14349 Therapeutic brain stimulation target anatomic site

C14350 Therapeutic brain stimulation anterior-posterior coordinates value

C14351 Therapeutic brain stimulation lateral coordinates value

C14352 Therapeutic brain stimulation depth coordinates value

C14353 Therapeutic brain stimulation placement method type

C14354 Therapeutic brain stimulation placement verification type

C14355 Therapeutic brain stimulation pulse frequency

C14356 Therapeutic brain stimulation pulse voltage value

C14357 Therapeutic brain stimulation pulse current value

C14358 Therapeutic brain stimulation pulse polarity type

C14359 Therapeutic brain stimulation pulse width value

C14360 Therapeutic brain stimulation pulse stimulus type

C14361 Therapeutic brain stimulation intermittent pulse on duration

C14362 Therapeutic brain stimulation intermittent pulse off duration

C14363 Therapeutic brain stimulation postoperative MRI verification indicator

C14364 Pathology temporal lobectomy temporal lobe finding text

C14365 Surgical language laterality type

C14366 Surgery intraoperative electrocorticogram type

C14367 Surgery intraoperative cortical stimulation mapping indicator

C14368 Surgery stereotaxis type

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C14369 Pathology temporal lobectomy hippocampus finding type
C14370 Pathology lesionectomy vascular finding type
C14371 Pathology lesionectomy tumor finding type
C14372 Pathology lesionectomy cortical dysplasia indicator
C14373 Pathology lesionectomy infectious or inflammatory finding type
C14374 Pathology lesionectomy congenital malformation finding type
C14375 Surgery pathology hospital day count
C14376 Surgery post-operative seizure indicator
C14377 Surgery post-operative seizure count
C14378 Surgery post-operative neurologic complication type
C14379 Surgery post-operative medical complication type
C14380 Surgery post-operative readmission 30 days after surgery indicator
C14381 Surgery post-operative return to operating room indicator
C14382 Surgery post-operative complication text
C14383 Surgery post-operative complication resolved date
C14384 Pathology lesionectomy trauma finding text
C17638 Surgery post-operative psychiatric complication text
C17639 Surgery post-operative readmission 30 days after surgery reason
C17640 Surgery post-operative respiratory complication text
C17641 Surgery post-operative return to operating room reason
C17643 Surgical or therapeutic procedure text
C18584 Surgery post-operative altered state complication text
C18585 Surgery post-operative aphasia complication text
C18586 Surgery post-operative gastrointestinal complication text
C18587 Surgery post-operative memory deficit complication text
C18917 Surgery lesionectomy resection extent other text
C18918 Surgery hemispherectomy other text
C18921 Therapeutic brain stimulation target anatomic other text
C18922 Therapeutic brain stimulation placement method other text
C18923 Therapeutic brain stimulation placement verification other text
C18924 Pathology lesionectomy tumor finding other text
C18925 Pathology lesionectomy infectious or inflammatory finding other text

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C18926 Surgery post-operative medical complication other text

January 2020 Revisions

- General Core CRF updated to replace 'Gender' question with 'Sex assigned at birth' and 'Gender identity'.
- Two new CDEs added to CRF: C58676 (Sex assigned at birth) and C58677 (Gender identity). C00035 has been removed
- Start-Up document updated to reflect these changes.

October 2019 Revisions

- Epilepsy seizure severity instrument recommendations added under the Outcomes and End Points Domain/ Patient Reported Outcomes Sub-Domain:
 - NINDS Epilepsy Seizure Severity Instrument Recommendations summary document
 - Liverpool Seizure Severity Scale 2.0 (LSSS 2.0) NOC: Supplemental
 - Seizure Severity Questionnaire (SSQ) V2.2 (Baseline and Follow-Up Versions) NOC: Supplemental

October 2018 Revisions

- Classification of Seizures:
 - Focal Generalized Unknown if generalized or focal Unclassified seizures on case report form
 - CDEs added: C58581 C58583 C58584 C58585 C58586 C58588 C58589 C58590 C58591 C58592 C58593 C58594 C58595 C58596 C58597 C58598 C58599 C58600 C58601 C58602 C58603 C58604 C58607
 - CDEs removed: C14126 C14127 C14130 C14125 C18500 C14132
- Classification of Etiology:
 - Specific Etiologies subdivided into: Genetic or presumed genetic Structural Metabolic/toxic Immune Infectious Unknown on case report form
 - CDEs added: C58580 C58582 C58587 C58605 C58606
 - CDEs removed: C14422 C14423 C14424 C18928 C18501 C18929 C18930 C20332
 - CDEs revised: C14425 C14426 C14427

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July 2018 Revisions

- Updated Epilepsy Quality of Life Instrument Recommendations to include an additional reference for the 31-Item Quality of Life in Epilepsy Inventory (QOLIE-31).
- Updated VA Toxicity Scale to include additional information and references.
- Updated Quality of Life in Epilepsy Inventory (QOLIE-31) to include additional information and references.

May 2018 Revisions

- Updated Epilepsy Quality of Life Instrument Recommendations to include additional information and references for the PedsQL™ Epilepsy Module.

July 2017 Revisions

Epilepsy QoL recommendations updated:

- Documents added/updated:
 - NINDS_Epilepsy_QoL_Instrument_Recommendations
 - Quality of Life in Childhood Epilepsy (QOLCE-55) NOC: Supplemental – Highly Recommended
 - Childhood Quality of Life in Epilepsy (CHEQOL) NOC: Supplemental
 - Quality of Life in Epilepsy Inventory (QOLIE-31) NOC: Supplemental – Highly Recommended
 - Neuro-QoL Measurement System NOC: Supplemental – Highly Recommended
- Documents removed:
 - Neuro-QoL Instruments Summary
 - Overview of Recommended Quality of Life Instruments
 - Recommended Quality of Life Instruments - Adult
 - Recommended Quality of Life Instruments - Pediatric
 - Healthy Days Core Module
 - Pediatric Quality of Life Inventory (PEDSQL)
 - Quality of Life in Epilepsy Inventory (QOLIE-48)

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- Quality of Life in Epilepsy Inventory (QOLIE-10)
- Quality of Life in Epilepsy Inventory (QOLIE-89)
- The DISABKIDS Chronic Generic Module (DCGM-37)

April 2015 Revisions

Overview

There have been changes to the content and structure of the Epilepsy CDE materials since the previous version was released in August 2012 including the following:

Form Status Changes

New Forms:

- None

Updated Forms:

- Hyperlinked all CRF references in the Overview of Instruments for Assessing Comorbidities
- Updated Dr. Ellen Grober's email address in the American National Adult Reading Test (AmNART) document.

Removed Forms:

- None

Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

1 Epilepsy Revision History Table

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Overview of Instruments for Assessing Comorbidities	3.0	2.0	Minor	New hyperlinks	Hyperlinks were added for those instruments missing them

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
American National Adult Reading Test (AmNART)			Minor	Email address updated	Updated contact information (email address) in the NOC

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March 2015 Revisions

Overview

Form Status Changes

New Forms:

No new forms

Updated Forms:

- NOCs revised: (classification changed from Core to Supplemental Highly-Recommended):
 - American National Adult Reading Test (AmNART)
 - Boston Naming Test (BNT)
 - Conner's Continuous Performance Test II Version 5
 - Controlled Oral Word Association Test (COWAT)
 - Hopkins Verbal Learning Test - Revised (HVLN-R)
 - Montreal Cognitive Assessment (MoCA)
- Start-Up Resources: added back the Supplemental - Highly Recommended CDEs from Classification of Seizures Classification of Etiology and Syndromes by Age of Onset CRFs.
- Social Status CRF: Changed the Classification for the two Core CDEs to Supplemental – Highly Recommended
- Classification of Etiology CRF: Added a new CDE to address the question: "If more than one specific etiology is selected specify:"
- Overview of Instruments for Assessing Comorbidities: Removed the sentences "Recommended as a Core instrument" from the footer and replaced with "Recommended as a Supplemental - Highly Recommended instrument."

Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent tab.

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
American National Adult Reading Test (AmNART)			Minor	Classification change	Classification changed from Core to Supplemental – Highly Recommended

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Boston Naming Test (BNT)			Minor	Classification change	Classification changed from Core to Supplemental – Highly Recommended
Conner's Continuous Performance Test II Version 5			Minor	Classification change	Classification changed from Core to Supplemental – Highly Recommended
Controlled Oral Word Association Test (COWAT)			Minor	Classification change	Classification changed from Core to Supplemental – Highly Recommended
Hopkins Verbal Learning Test - Revised (HVLTR)			Minor	Classification change	Classification changed from Core to Supplemental – Highly Recommended
Montreal Cognitive Assessment (MoCA)			Minor	Classification change	Classification changed from Core to Supplemental – Highly Recommended
Start-Up Resources			Minor	Added CDEs	Added previously removed Supplemental – Highly Recommended CDEs
Social Status	3.0	2.0	Minor	Changed classifications	Classification changes for two Core CDEs to Supplemental – Highly Recommended
Classification of Etiology	3.0	2.0	Minor	CDE added	New CDE was added
Overview of Instruments for Assessing Comorbidities			Minor	Changed footers	Revised references to Supplemental – Highly Recommended

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February 2015 Revisions

No changes.

January 2015 Revisions

Overview

- Dr. Nicholas Barbaro and Dr. Daniel Lowenstein were set as Co-Chairs of the Epilepsy Oversight Committee
- Changes to Epilepsy CDEs from Core to Supplemental for:
 - Classification of Etiology
 - Classification of Seizures
 - Syndromes by Age of Onset

Form Status Changes

New Forms:

No new forms

Updated Forms:

- Adverse Event Tracking Log
- AED Plasma Concentration Log
- Anti-Epileptic Drug (AED) Log
- Classification of Etiology
- Classification of Seizures
- Demographics
- Devices Log
- Non Anti Epileptic Medication Log
- Scalp EEG
- Surgery and Pathology

Removed Forms:

- General Physical and Neurological Exam

Epilepsy CDE Revision History Document

Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included in the table on the subsequent page.

3 Epilepsy Revision History Table

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
All	Varies by form (all 1.X)	Varies by form (all 1.X)	Minor	Modified CDEs	Nearly all CDE names and definitions were updated to achieve greater consistency across all NINDS CDEs and for clarity
Various	Varies by form (all 1.X)	Varies by form (all 1.X)	Minor	Deleted CDEs	The following types of CDEs were deleted: CDEs redundant with other CDEs; CDEs specifying unit; and CDEs specifying an "other specify" response
Various	Varies by form (all 1.X)	Varies by form (all 1.X)	Minor	Modified CDEs	For a number of CDEs "Unknown" was added to the permissible value set and in some cases "Unknown" replaced "Unknown/Don't Know"
Various	Varies by form (all 1.X)	Varies by form (all 1.X)	Minor	Modified Forms	Instructions were updated to include additional details.
Adverse Event Tracking Log	1.2	1.1	Minor	Modified Form	Modified AE tracking log to make consistent with General CDEs.
Adverse Event Tracking Log	1.2	1.1	Minor	Modified Form	Removed Core designation for CDEs on form to indicate instead that the CDEs are recommended for prospective intervention studies.
AED Plasma Concentration Log	1.2	1.1	Minor	Modified Form	Relabeled form name; added instructions indicating the form is to be used with the AED Drug Log; removed original Table 1 listing dose units.

Epilepsy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Anti Epileptic Drug Log	1.2	1.1	Minor	Modified CDEs	The Drug Log and associated CDEs were modified to be consistent with the General Prior and Concomitant Medications CDEs.
Anti Epileptic Drug Log	1.2	1.1	Minor	Modified CDEs	Medication prior or concomitant discontinuation reason PVs were modified.
Classification of Etiology	1.2	1.1	Minor	Modified CDEs	Changed permissible values for indicating whether etiology is present (PG14125)
Classification of Etiology	1.2	1.1	Minor	Modified Form	Updated to indicate that all CDEs on form are Core.
Classification of Seizures	1.3	1.2	Minor	Modified CDEs	Changed permissible values for indicating whether seizure is present (PG14125)
Classification of Seizures	1.3	1.2	Minor	New CDEs	Added Seizures distinct likelihood type Data collected date and time Data valid through date and time
Demographics	1.3	1.2	Minor	Modified Form	Several CDEs were moved from this CRF to other CRFs where they are more appropriate
Demographics	1.3	1.2	Minor	Modified Form	Added Language primary text and Language primary ISO 639-2 code
Devices Log	1.2	1.1	Minor	Modified form	Minor formatting changes to form.
Devices Log	1.2	1.1	Minor	Modified Form	Removed Core designation for CDEs on form to indicate instead that the CDEs are recommended for prospective intervention studies.
Neurological Exam	1.3	1.2	Minor	New Form	General Physical and Neurological Exam form was split into two forms: Physical Exam and Neurological Exam.
Neuropsychological Testing Background Information	1.0	N/A	Minor	New Form	Neuropsychological Testing Background Information CRF was created to include relevant CDEs previously captured on the Demographics form.

Epilepsy CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Non Anti Epileptic Medication Log	1.2	1.1	Minor	New CDEs	Added Medication prior or concomitant dose frequency and Medication prior or concomitant PRN average monthly frequency
Physical Exam	1.3	1.2	Minor	Added CDEs	Added Hand preference type
Physical Exam	1.3	1.2	Minor	Modified CDEs	Modified Body System category and Physical exam body system result PVs
Physical Exam	1.3	1.2	Minor	Modified Form	Several CDEs were removed from the form including Type of Exam Height Weight and Head circumference. Height Weight and Head circumference already are included on the Vital Signs form.
Physical Exam	1.3	1.2	Minor	New Form	General Physical and Neurological Exam form was split into two forms: Physical Exam and Neurological Exam.
Scalp EEG	1.2	1.2	Minor	Modified Form	Numbering was added to form.
Social Status	1.1	N/A	Minor	New Form	Social Status CRF was created to include relevant CDEs previously captured on the Demographics form.
Surgery and Pathology	1.1	1.1	Minor	Modified Form	Removed place to capture patient's name. Moved Stimulus Parameters to a new page for readability.
Vital Signs	1.1	1.0	Minor	New Form	A Vital Signs form was added using the General elements.

Epilepsy CDE Revision History Document

November 2014 Revisions

- Changes to the ordering of the Neuropsychological Subdomain in Epilepsy to list the Instrument Recommendation documents above the Neuropsychological Testing Background Information CRF.
- Classification changes to NOCs in Epilepsy. The ADHD Comprehensive Teachers Rating Scale (ACTeRS) and Adolescent Symptom Inventory (ASI) were changed from Core to Supplemental.

September 2014 Revisions

No changes.

August 2014 Revisions

No changes.

July 2014 Revisions

No changes.

June 2014 Revisions

No changes.

May 2014 Revisions

No changes.

April 2014 Revisions

No changes.

March 2014 Revisions

No changes.

February 2014 Revisions

No changes.

January 2014 Revisions

No changes.

December 2013 Revisions

- Updated highlight summaries and start-up resource documents for Epilepsy.

Epilepsy CDE Revision History Document

November 2013 Revisions

No changes.

August 2012 Revisions

Overview

Additional improvements have been made following the latest meeting of the Epilepsy CDE Oversight Committee in June 2012.

Form Status Changes

New Forms:

- Neuro-QOL Instruments Summary

Updated Forms:

- Recommended Psychiatric Instruments
- Adverse Event Reporting Instruments
- Recommended QOL Instruments-Adult
- Recommended QOL Instruments-Pediatric

Removed Forms:

- N/A - No removed forms

Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

Epilepsy CDE Revision History Document

4 Epilepsy Revision History Table

CRF Module/ Guideline	Implementatio n Date	Curren t Versio n	Previou s Version	Change Classificatio n	Change Type	Description of Change
Recommend ed Psychiatric Instruments	August 2012	1.2	1.1	Minor	Modified Guidelin e	The instrument summary for the World Health Organization (WHO) Composite International Diagnostic Interview (WMH- CIDI) that is provided in the guidance document has been expanded to list the DSM disorders assessed by the measure
Recommend ed Adverse Event Reporting Instruments	August 2012	1.2	1.1	Minor	Modified Guidelin e	Adverse Events Profile: The number of items has been corrected from 19 to 21
Neuro-QOL Instruments Summary	August 2012	1.0	N/A	Minor	New Guidelin e	The NeuroQOL effort has been reviewed by the Epilepsy CDE Oversight Committee and a summary has been written for inclusion in the CDEs

Epilepsy CDE Revision History Document

CRF Module/ Guideline	Implementatio n Date	Curren t Versio n	Previou s Version	Change Classificatio n	Change Type	Description of Change
Recommend ed QOL Instruments- Adult	August 2012	1.1	1.0	Minor	Modified Guidelin e	These recommendation s have been reviewed by the Epilepsy CDE Oversight Committee and the references have been updated. No additional measures have been included.
Recommend ed QOL Instruments- Pediatric	August 2012	1.1	1.0	Minor	Modified Guidelin e	These recommendation s have been reviewed by the Epilepsy CDE Oversight Committee and the references have been updated. No additional measures have been included.

February 2012 Revisions

Overview

Improvements have been made following the first meeting of the Epilepsy CDE Oversight Committee in December 2011. Several elements have been moved from 'Core' to 'Supplemental' and minor administrative changes have been made.

Form Status Changes:

New Forms:

- N/A - No new forms

Epilepsy CDE Revision History Document

Updated Forms:

Demographics

General Physical and Neurological Exam

Scalp EEG

Classification of Epilepsy Syndromes

Classification of Seizures

Removed Forms:

N/A - No removed forms

Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

Epilepsy CDE Revision History Document

5 Epilepsy Revision History Table

CRF Module/ Guideline	Implementati on Date	Curren t Versio n	Previou s Version	Change Classificatio n	Change Type	Description of Change
Demographi cs	February 2012	1.2	1.1	Minor	Reclassificati on of CDEs	The following CDEs have been moved from 'Core' to 'Supplemental': “Handedness” – This is not relevant for all studies and should be Supplemental (except for neuropsychologi cal studies). “Employment” – This is not relevant for all studies and should be Supplemental. “English Primary Language” – This is not relevant for all studies and should be Supplemental.

Epilepsy CDE Revision History Document

CRF Module/ Guideline	Implementati on Date	Curren t Versio n	Previou s Version	Change Classificatio n	Change Type	Description of Change
General Physical and Neurological Exam	February 2012	1.2	1.1	Minor	Reclassificati on of CDEs	All CDES associated with this CRF Module have been reclassified as 'Supplemental'. If the study is going to conduct a physical exam investigators should consider these elements but there may be some studies where a physical exam is not appropriate or could be abbreviated.
Scalp EEG	February 2012	1.2	1.1	Minor	Modified Form	A notation has been added to the EEG CRF Instructions page noting these CDEs are not appropriate for ICU use.
Classificatio n of Epilepsy Syndromes	February 2012	1.2	1.1	Minor	Modified Form	The table for 'Other' has been moved to the top of the form since most patients are non-syndromic and a minor typo has been corrected.
Classificatio n of Seizures	February 2012	1.2	1.1	Minor	Modified Form	A minor typo has been corrected.

Epilepsy CDE Revision History Document

September 2011 Revisions

Overview

There have been many structural and formatting changes to improve the Epilepsy CDE materials since Version 1.0 was released in October 2010. Specific changes include the following:

- The header of all case report form (CRF) modules or “forms” was revised to be consistent with other NINDS CDE forms;
- The version number of all forms was updated (Version 1.1 vs. Version 1.0);
- Many element definitions and form instructions were improved and now provide additional clarification; and
- All elements related to a form not being completed or a test not being performed (e.g. Form not Done) were removed.
- The corresponding data dictionaries and Manuals of Procedures (MOPs) have been modified in accordance with the form changes.
- Prior to the September 2011 revisions (i.e. the Version 1.1 release) the NINDS CDE Team worked to harmonize the Epilepsy CDEs with the General CDEs and other disease-specific CDEs. Listed below are those forms that were revised beyond the structural and formatting changes described above due to the harmonization work.

Form Status Changes

New Forms:

- N/A - No new forms

Updated Forms:

- Demographics
- General Physical and Neurological Exam
- Adverse Event Tracking Log

Removed Forms:

- N/A - No removed forms

Detailed Form Revisions:

N/A- No Form Revisions

Epilepsy CDE Revision History Document

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

6 Epilepsy Revision History Table

CRF Module/ Guideline	Implementation Date	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Demographics	September 2011	1.1	1.0	Major	Modified CDEs	The permissible values/codes for the following CDEs were modified: Education Level and Education Level for pediatric participant/subject's mother
General Physical and Neurological Exam	September 2011	1.1	1.0	Minor	Modified Form	A number of the questions on the CRF were restructured into tabular format
Adverse Events Tracking Log	September 2011	1.1	1.0	Minor	Deleted CDEs	The following CDE was deleted: AE Sequence Number
Adverse Events Tracking Log	September 2011	1.1	1.0	Major	Modified CDEs	The permissible values/codes for the following CDEs were modified: Severity Relatedness Action Taken with Study Intervention