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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
C59400  Surgery diagnostic electrode epidural temporal laterality type
C59411  Surgery diagnostic electrode epidural parietal laterality type
C59412  Surgery diagnostic electrode epidural occipital laterality type
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
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
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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
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
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
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
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
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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
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
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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
C14369 Pathology temporal lobectomy hippocampus finding type
C14370 Pathology lesionectomy vascular finding type
C14371 Pathology lesionectomy tumor finding type
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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
C18926 Surgery post-operative medical complication other text
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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)
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

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<td>Hyperlinks were added for those instruments missing them</td>
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<td>American National Adult Reading Test (AmNART)</td>
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<td>Email address updated</td>
<td>Updated contact information (email address) in the NOC</td>
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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 (HVLT-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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</tr>
</tbody>
</table>
Epilepsy CDE Revision History Document

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
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

<table>
<thead>
<tr>
<th>CRF Module/ Guideline</th>
<th>Current Version</th>
<th>Previous Version</th>
<th>Change Classification</th>
<th>Change Type</th>
<th>Description of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>Varies by form (all 1.X)</td>
<td>Varies by form (all 1.X)</td>
<td>Minor</td>
<td>Modified CDEs</td>
<td>Nearly all CDE names and definitions were updated to achieve greater consistency across all NINDS CDEs and for clarity</td>
</tr>
<tr>
<td>Various</td>
<td>Varies by form (all 1.X)</td>
<td>Varies by form (all 1.X)</td>
<td>Minor</td>
<td>Deleted CDEs</td>
<td>The following types of CDEs were deleted: CDEs redundant with other CDEs; CDEs specifying unit; and CDEs specifying an &quot;other specify&quot; response</td>
</tr>
<tr>
<td>Various</td>
<td>Varies by form (all 1.X)</td>
<td>Varies by form (all 1.X)</td>
<td>Minor</td>
<td>Modified CDEs</td>
<td>For a number of CDEs &quot;Unknown&quot; was added to the permissible value set and in some cases &quot;Unknown&quot; replaced &quot;Unknown/Don't Know&quot;</td>
</tr>
<tr>
<td>Various</td>
<td>Varies by form (all 1.X)</td>
<td>Varies by form (all 1.X)</td>
<td>Minor</td>
<td>Modified Forms</td>
<td>Instructions were updated to include additional details.</td>
</tr>
<tr>
<td>Adverse Event Tracking Log</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified Form</td>
<td>Modified AE tracking log to make consistent with General CDEs.</td>
</tr>
<tr>
<td>Adverse Event Tracking Log</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified Form</td>
<td>Removed Core designation for CDEs on form to indicate instead that the CDEs are recommended for prospective intervention studies.</td>
</tr>
<tr>
<td>AED Plasma Concentration Log</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified Form</td>
<td>Relabeled form name; added instructions indicating the form is to be used with the AED Drug Log; removed original Table 1 listing dose units.</td>
</tr>
<tr>
<td>CRF Module/ Guideline</td>
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<td>Description of Change</td>
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<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Anti Epileptic Drug Log</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified CDEs</td>
<td>The Drug Log and associated CDEs were modified to be consistent with the General Prior and Concomitant Medications CDEs.</td>
</tr>
<tr>
<td>Anti Epileptic Drug Log</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified CDEs</td>
<td>Medication prior or concomitant discontinuation reason PVs were modified.</td>
</tr>
<tr>
<td>Classification of Etiology</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified CDEs</td>
<td>Changed permissible values for indicating whether etiology is present (PG14125)</td>
</tr>
<tr>
<td>Classification of Etiology</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified Form</td>
<td>Updated to indicate that all CDEs on form are Core.</td>
</tr>
<tr>
<td>Classification of Seizures</td>
<td>1.3</td>
<td>1.2</td>
<td>Minor</td>
<td>Modified CDEs</td>
<td>Changed permissible values for indicating whether seizure is present (PG14125)</td>
</tr>
<tr>
<td>Classification of Seizures</td>
<td>1.3</td>
<td>1.2</td>
<td>Minor</td>
<td>New CDEs</td>
<td>Added Seizures distinct likelihood type Data collected date and time Data valid through date and time</td>
</tr>
<tr>
<td>Demographics</td>
<td>1.3</td>
<td>1.2</td>
<td>Minor</td>
<td>Modified Form</td>
<td>Several CDEs were moved from this CRF to other CRFs where they are more appropriate</td>
</tr>
<tr>
<td>Demographics</td>
<td>1.3</td>
<td>1.2</td>
<td>Minor</td>
<td>Modified Form</td>
<td>Added Language primary text and Language primary ISO 639-2 code</td>
</tr>
<tr>
<td>Devices Log</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified form</td>
<td>Minor formatting changes to form.</td>
</tr>
<tr>
<td>Devices Log</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified Form</td>
<td>Removed Core designation for CDEs on form to indicate instead that the CDEs are recommended for prospective intervention studies.</td>
</tr>
<tr>
<td>Neurological Exam</td>
<td>1.3</td>
<td>1.2</td>
<td>Minor</td>
<td>New Form</td>
<td>General Physical and Neurological Exam form was split into two forms: Physical Exam and Neurological Exam.</td>
</tr>
<tr>
<td>Neuropsychological Testing</td>
<td>1.0</td>
<td>N/A</td>
<td>Minor</td>
<td>New Form</td>
<td>Neuropsychological Testing Background Information CRF was created to include relevant CDEs previously captured on the Demographics form.</td>
</tr>
<tr>
<td>CRF Module/ Guideline</td>
<td>Current Version</td>
<td>Previous Version</td>
<td>Change Classification</td>
<td>Change Type</td>
<td>Description of Change</td>
</tr>
<tr>
<td>---------------------------------------</td>
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<td>-----------------------</td>
<td>-------------</td>
<td>---------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Non Anti Epileptic Medication Log</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>New CDEs</td>
<td>Added Medication prior or concomitant dose frequency and Medication prior or concomitant PRN average monthly frequency</td>
</tr>
<tr>
<td>Physical Exam</td>
<td>1.3</td>
<td>1.2</td>
<td>Minor</td>
<td>Added CDEs</td>
<td>Added Hand preference type</td>
</tr>
<tr>
<td>Physical Exam</td>
<td>1.3</td>
<td>1.2</td>
<td>Minor</td>
<td>Modified CDEs</td>
<td>Modified Body System category and Physical exam body system result PVs</td>
</tr>
<tr>
<td>Physical Exam</td>
<td>1.3</td>
<td>1.2</td>
<td>Minor</td>
<td>Modified Form</td>
<td>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.</td>
</tr>
<tr>
<td>Physical Exam</td>
<td>1.3</td>
<td>1.2</td>
<td>Minor</td>
<td>New Form</td>
<td>General Physical and Neurological Exam form was split into two forms: Physical Exam and Neurological Exam.</td>
</tr>
<tr>
<td>Scalp EEG</td>
<td>1.2</td>
<td>1.2</td>
<td>Minor</td>
<td>Modified Form</td>
<td>Numbering was added to form.</td>
</tr>
<tr>
<td>Social Status</td>
<td>1.1</td>
<td>N/A</td>
<td>Minor</td>
<td>New Form</td>
<td>Social Status CRF was created to include relevant CDEs previously captured on the Demographics form.</td>
</tr>
<tr>
<td>Surgery and Pathology</td>
<td>1.1</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified Form</td>
<td>Removed place to capture patient's name. Moved Stimulus Parameters to a new page for readability.</td>
</tr>
<tr>
<td>Vital Signs</td>
<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>New Form</td>
<td>A Vital Signs form was added using the General elements.</td>
</tr>
</tbody>
</table>
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.
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 Table

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<thead>
<tr>
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<th>Description of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommended Psychiatric Instruments</td>
<td>August 2012</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified Guideline</td>
<td>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</td>
</tr>
<tr>
<td>Recommended Adverse Event Reporting Instruments</td>
<td>August 2012</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified Guideline</td>
<td>Adverse Events Profile: The number of items has been corrected from 19 to 21</td>
</tr>
<tr>
<td>NeuroQOL Instruments Summary</td>
<td>August 2012</td>
<td>1.0</td>
<td>N/A</td>
<td>Minor</td>
<td>New Guideline</td>
<td>The NeuroQOL effort has been reviewed by the Epilepsy CDE Oversight Committee and a summary has been written for inclusion in the CDEs</td>
</tr>
</tbody>
</table>
### 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

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</tr>
</thead>
<tbody>
<tr>
<td>Recommended QOL Instruments - Adult</td>
<td>August 2012</td>
<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified Guideline</td>
<td>These recommendations have been reviewed by the Epilepsy CDE Oversight Committee and the references have been updated. No additional measures have been included.</td>
</tr>
<tr>
<td>Recommended QOL Instruments - Pediatric</td>
<td>August 2012</td>
<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified Guideline</td>
<td>These recommendations have been reviewed by the Epilepsy CDE Oversight Committee and the references have been updated. No additional measures have been included.</td>
</tr>
</tbody>
</table>

---
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 Table

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<tbody>
<tr>
<td>Demographics</td>
<td>February 2012</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Reclassification of CDEs</td>
<td>The following CDEs have been moved from 'Core' to 'Supplemental': “Handedness” – This is not relevant for all studies and should be Supplemental (except for neuropsychological 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.</td>
</tr>
<tr>
<td>CRF Module/ Guideline</td>
<td>Implementation Date</td>
<td>Current Version</td>
<td>Previous Version</td>
<td>Change Classification</td>
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<td>Description of Change</td>
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<td>----------------------------------------</td>
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<td>------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>General Physical and Neurological Exam</td>
<td>February 2012</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Reclassification of CDEs</td>
<td>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.</td>
</tr>
<tr>
<td>Scalp EEG</td>
<td>February 2012</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified Form</td>
<td>A notation has been added to the EEG CRF Instructions page noting these CDEs are not appropriate for ICU use.</td>
</tr>
<tr>
<td>Classification of Epilepsy Syndromes</td>
<td>February 2012</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified Form</td>
<td>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.</td>
</tr>
<tr>
<td>Classification of Seizures</td>
<td>February 2012</td>
<td>1.2</td>
<td>1.1</td>
<td>Minor</td>
<td>Modified Form</td>
<td>A minor typo has been corrected.</td>
</tr>
</tbody>
</table>
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
Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

### 6 Epilepsy Revision History Table

<table>
<thead>
<tr>
<th>CRF Module/ Guideline</th>
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<th>Change Type</th>
<th>Description of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td>September 2011</td>
<td>1.1</td>
<td>1.0</td>
<td>Major</td>
<td>Modified</td>
<td>CDEs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>The permissible values/codes for the following CDEs were modified: Education Level and Education Level for pediatric participant/subject's mother</td>
</tr>
</tbody>
</table>
| General Physical and Neurological Exam | September 2011 | 1.1 | 1.0 | Minor | Modified Form | A number of the questions on the CRF were restruc
| 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 |