

Epilepsy CDE Revision History Document

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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)

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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

Epilepsy CDE Revision History Document

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 (HVLTR)
 - 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.

2 Epilepsy Revision History Table

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

Epilepsy CDE Revision History Document

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

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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.

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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.

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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.

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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.

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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.

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4 Epilepsy Revision History Table

CRF Module/ Guideline	Implementation Date	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Recommended Psychiatric Instruments	August 2012	1.2	1.1	Minor	Modified Guideline	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
Recommended Adverse Event Reporting Instruments	August 2012	1.2	1.1	Minor	Modified Guideline	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 Guideline	The NeuroQOL effort has been reviewed by the Epilepsy CDE Oversight Committee and a summary has been written for inclusion in the CDEs

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CRF Module/ Guideline	Implementation Date	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Recommended QOL Instruments-Adult	August 2012	1.1	1.0	Minor	Modified Guideline	These recommendations have been reviewed by the Epilepsy CDE Oversight Committee and the references have been updated. No additional measures have been included.
Recommended QOL Instruments-Pediatric	August 2012	1.1	1.0	Minor	Modified Guideline	These recommendations 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

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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.

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5 Epilepsy Revision History Table

CRF Module/ Guideline	Implementation Date	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Demographics	February 2012	1.2	1.1	Minor	Reclassification 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 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.

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CRF Module/ Guideline	Implementation Date	Current Version	Previous Version	Change Classification	Change Type	Description of Change
General Physical and Neurological Exam	February 2012	1.2	1.1	Minor	Reclassification 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.
Classification 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.
Classification of Seizures	February 2012	1.2	1.1	Minor	Modified Form	A minor typo has been corrected.

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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

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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