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:
  
  o NINDS_Epilepsy_QoL_Instrument_Recommendations

  o Quality of Life in Childhood Epilepsy (QOLCE-55) NOC: Supplemental – Highly Recommended

  o Childhood Quality of Life in Epilepsy (CHEQOL) NOC: Supplemental

  o Quality of Life in Epilepsy Inventory (QOLIE-31) NOC: Supplemental – Highly Recommended

  o Neuro-QoL Measurement System NOC: Supplemental – Highly Recommended

• Documents removed:

  o Neuro-Qol Instruments Summary

  o Overview of Recommended Quality of Life Instruments

  o Recommended Quality of Life Instruments - Adult

  o Recommended Quality of Life Instruments - Pediatric

  o Healthy Days Core Module

  o Pediatric Quality of Life Inventory (PEDSQL)

  o 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

<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>Overview of Instruments for Assessing Comorbidities</td>
<td>3.0</td>
<td>2.0</td>
<td>Minor</td>
<td>New hyperlinks</td>
<td>Hyperlinks were added for those instruments missing them</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>
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<td>------------------------------------------------------------</td>
</tr>
<tr>
<td>American National Adult Reading Test (AmNART)</td>
<td></td>
<td></td>
<td>Minor</td>
<td>Email address updated</td>
<td>Updated contact information (email address) in the NOC</td>
</tr>
</tbody>
</table>
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.

2 Epilepsy Revision History Table

<table>
<thead>
<tr>
<th>CRF Module/ Guideline</th>
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<th>Description of Change</th>
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</thead>
<tbody>
<tr>
<td>American National Adult Reading Test (AmNART)</td>
<td></td>
<td></td>
<td>Minor</td>
<td>Classification change</td>
<td>Classification changed from Core to Supplemental – Highly Recommended</td>
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<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>
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<tr>
<td>Boston Naming Test (BNT)</td>
<td></td>
<td>Minor</td>
<td>Classification change</td>
<td></td>
<td>Classification changed from Core to Supplemental – Highly Recommended</td>
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<tr>
<td>Conner's Continuous Performance Test II, Version 5</td>
<td></td>
<td>Minor</td>
<td>Classification change</td>
<td></td>
<td>Classification changed from Core to Supplemental – Highly Recommended</td>
</tr>
<tr>
<td>Controlled Oral Word Association Test (COWAT)</td>
<td></td>
<td>Minor</td>
<td>Classification change</td>
<td></td>
<td>Classification changed from Core to Supplemental – Highly Recommended</td>
</tr>
<tr>
<td>Hopkins Verbal Learning Test - Revised (HVLT-R)</td>
<td></td>
<td>Minor</td>
<td>Classification change</td>
<td></td>
<td>Classification changed from Core to Supplemental – Highly Recommended</td>
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<tr>
<td>Montreal Cognitive Assessment (MoCA)</td>
<td></td>
<td>Minor</td>
<td>Classification change</td>
<td></td>
<td>Classification changed from Core to Supplemental – Highly Recommended</td>
</tr>
<tr>
<td>Start-Up Resources</td>
<td></td>
<td>Minor</td>
<td>Added CDEs</td>
<td></td>
<td>Added previously removed Supplemented – Highly Recommended</td>
</tr>
<tr>
<td>Social Status</td>
<td>3.0</td>
<td>2.0</td>
<td>Minor</td>
<td>Changed classifications</td>
<td>Classification changes for two Core CDEs to Supplemental – Highly Recommended</td>
</tr>
<tr>
<td>Classification of Etiology</td>
<td>3.0</td>
<td>2.0</td>
<td>Minor</td>
<td>CDE added</td>
<td>New CDE was added</td>
</tr>
<tr>
<td>Overview of Instruments for Assessing Comorbidities</td>
<td></td>
<td>Minor</td>
<td>Changed footers</td>
<td></td>
<td>Revised references to Supplemented – Highly Recommended</td>
</tr>
</tbody>
</table>
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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
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>
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<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>
<td>Current Version</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 Background Information</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>
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<td>Description of Change</td>
</tr>
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<td>---------------------------</td>
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<td>------------------</td>
<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>
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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.
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.
| CRF Module/ Guideline               | Implementa
| Date                | Curren
| t Version | Previou
| s 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 |
## 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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<table>
<thead>
<tr>
<th>CRF Module/ Guideline</th>
<th>Implementation Date</th>
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<th>Description of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommended QOL Instruments- Adult</strong></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><strong>Recommended QOL Instruments- Pediatric</strong></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.
### Demographics

<table>
<thead>
<tr>
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<th>Description of Change</th>
</tr>
</thead>
<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>
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<td>Description of Change</td>
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<td>---------------------------------------------</td>
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<td>-----------------------</td>
<td>-------------</td>
<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>
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
6 Epilepsy Revision History Table

<table>
<thead>
<tr>
<th>CRF Module/ Guideline</th>
<th>Implementation Date</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>Demographics</td>
<td>September 2011</td>
<td>1.1</td>
<td>1.0</td>
<td>Major</td>
<td>Modified CDEs</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>
<tr>
<td>General Physical and Neurological Exam</td>
<td>September 2011</td>
<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified Form</td>
<td>A number of the questions on the CRF were restructured into tabular format</td>
</tr>
<tr>
<td>Adverse Events Tracking Log</td>
<td>September 2011</td>
<td>1.1</td>
<td>1.0</td>
<td>Minor</td>
<td>Deleted CDEs</td>
<td>The following CDE was deleted: AE Sequence Number</td>
</tr>
<tr>
<td>Adverse Events Tracking Log</td>
<td>September 2011</td>
<td>1.1</td>
<td>1.0</td>
<td>Major</td>
<td>Modified CDEs</td>
<td>The permissible values/codes for the following CDEs were modified: Severity, Relatedness, Action Taken with Study Intervention</td>
</tr>
</tbody>
</table>