

# General CDE Revision History Document

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# General CDE Revision History Document

## October 2024 Revisions

The following case report forms (CRFs) were updated. The corresponding data dictionaries (i.e., CDE Detail Reports) have been modified in accordance with the form changes. All new CDEs were classified as Supplemental. Updates to add social determinants of health (SDOH) related CDEs to the Demographics CRF were harmonized with Science collaborative for Health disparities and Artificial intelligence bias REduction (SchARE) CDEs from the National Institute on Minority Health and Health Disparities (NIMHD). Updates to adverse events (AE)/serious adverse events (SAE) related CRFs include changes to reflect current U.S. Food and Drug Administration (FDA) guidance, Cancer Therapy Evaluation Program (CTEP) guidance, and Clinical Data Interchange Standards Consortium (CDISC) standards.

1. Adverse Events F0009
  - a. CDEs Added
    - i. C60386 Adverse event site aware date and time
    - ii. C60387 Adverse event ongoing indicator
    - iii. C60388 Adverse event severity intensity CDISC grade
    - iv. C60389 Adverse event study intervention action take type other text
  - b. CDEs Removed
    - i. C02305 Adverse event severity scale grade
    - ii. C22703 Serious adverse event form completion indicator
  - c. Classification Changes
    - i. None
  - d. Permissible Value Modifications
    - i. C02308 Adverse event during study indicator; C02303 Adverse event outcome status; C02309 Serious adverse event indicator
      1. Removed: Unknown
    - ii. C02304 Adverse event study intervention relatedness investigator assessment grade
      1. Added: Possible; Probable
      2. Removed: Reasonable Possibility
    - iii. C02300 Adverse event study intervention action take type
      1. Added: Other, specify
2. Death Report F0021
  - a. CDEs Added
    - i. C22780 Date time clock type
    - ii. C60367 Autopsy indicator
    - iii. C60368 Death certificate status
  - b. CDEs Removed
    - i. None
  - c. Classification Changes
    - i. None
  - d. Permissible Value Modifications
    - i. None
3. Demographics F0016
  - a. CDEs Added
    - i. C12611 Birth location state name
    - ii. C18863 Birth location state other text
    - iii. C00005 Birth country name

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- iv. C00004 Birth country ISO code
- v. C18385 Birth time
- vi. C22780 Date time clock type
- b. CDEs Removed
  - i. None
- c. Classification Changes
  - i. None
- d. Permissible Value Modifications
  - i. None
- 4. Serious Adverse Events F0004
  - a. CDEs Added
    - i. C60369 Serious adverse event site aware date and time
    - ii. C60370 Serious adverse event ongoing indicator
    - iii. C60371 Serious adverse event result death indicator
    - iv. C60372 Serious adverse event threaten life indicator
    - v. C60373 Serious adverse event initial prolong hospital indicator
    - vi. C60374 Serious adverse event intervention require prevent permanent impairment damage indicator
    - vii. C60375 Serious adverse event result persistent significant disability incapacity indicator
    - viii. C60376 Serious adverse event associate congenital anomaly birth defect indicator
    - ix. C60377 Serious adverse event other important medical event indicator
    - x. C60378 Serious adverse event other important medical event text
    - xi. C60379 Study intervention name
    - xii. C60380 Serious adverse event cause discontinue study indicator
    - xiii. C60381 Serious adverse event investigator assessment reason other text
    - xiv. C60382 Principal investigator name
    - xv. C60383 Principal investigator address text
    - xvi. C60384 Adverse event report identifier telephone number
    - xvii. C60385 Serious adverse event sponsor assessment indicator
  - b. CDEs Removed
    - i. C20391 Sex type
    - ii. C00008 Age value
    - iii. C01541 Weight measurement
    - iv. C01581 Weight unit of measure
    - v. C01522 Height measurement
    - vi. C01582 Height unit of measure
    - vii. C20410 Serious adverse event not resolution indicator
    - viii. C17447 Event description text
    - ix. C20412 Serious adverse event outcome status
    - x. C04802 Death date and time
    - xi. C20411 Serious adverse event outcome status other text
    - xii. C19256 Study protocol name
    - xiii. C12232 Laboratory director name
  - c. Classification Changes
    - i. None
  - d. Permissible Value Modifications

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- i. C20399 Serious adverse event end study intervention indicator; C20400 Serious adverse event resolve end study intervention indicator; C20402 Study blind broken indicator
  - 1. Removed: N/A
- ii. C20403 Serious adverse event investigator assessment reason
  - 1. Added: Other, specify
  - 2. Revised: Concomitant medication to Concomitant medication, specify; Concurrent disorder to Concurrent disorder, specify; Withdrawal of study intervention to Withdrawal of study intervention, specify

## General CDE Revision History Document

### May 2024 Revisions

- Replaced the PROMIS instrument NOC with domain-specific NOC for the following item banks or short forms

PROMIS Item Bank or Short Form	New Domain-Specific NOC
PROMIS Item Bank v1.0 - Social Activity	PROMIS Ability to Participate Item Bank and Short Forms
PROMIS Item Bank v1.1 - Pain Behavior	PROMIS Pain Behavior Item Bank and Short Form
PROMIS Pediatric Item Bank v1.0 - Pain Behavior-Short Form 8a	
PROMIS Item Bank v1.1 - Pain Interference	PROMIS Pain Interference Item Bank

- Updated the overall Patient-Reported Outcomes Measurement Information System (PROMIS) and PROMIS Scale v1.2 - Global Health NOCs to align with the new standardized text and format for PROMIS NOCs.

### January 2024 Revisions

- Replaced the PROMIS instrument NOC with domain-specific NOC for the following item banks or short forms

PROMIS Item Bank or Short Form	New Domain-Specific NOC
PROMIS Item Bank v2.0 - Cognitive Function	PROMIS Cognitive Function Item Banks
PROMIS Item Bank v1.0 - Applied Cognition - Abilities	
PROMIS Item Bank v1.0 - Applied Cognition - General Concerns	
PROMIS Item Bank v1.0 - Self-Efficacy for Managing Emotions	PROMIS Self-Efficacy for Managing Chronic Conditions Item Bank
PROMIS Item Bank v1.0 - Sleep Disturbance	PROMIS Sleep Item Banks
PROMIS Item Bank v1.0 - Sleep Related Impairment	

### November 2023 Revisions

- Updated the Data Standards page text to include links to the Parkinson’s Disease Digital Technology Guidance Documents.
- Added the following CDEs to the Medical History CRF (F0013) as Supplemental:

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- C59686 COVID-19 status reason
  - C59687 COVID-19 first date
  - C59688 COVID-19 first date not applicable status
  - C59689 COVID-19 vaccine or clinical vaccine trial status
- Replaced the PROMIS instrument NOC with domain-specific NOC for the following item banks or short forms

PROMIS Item Bank or Short Form	New Domain-Specific NOC
PROMIS Item Bank v1.0 - Alcohol - Positive Consequences	PROMIS Alcohol Use Item Banks
PROMIS Item Bank v1.0 - Alcohol - Positive Expectancies	
PROMIS Item Bank v1.0 - Alcohol Use	
PROMIS Item Bank v1.0 - Alcohol: Negative Consequences	
PROMIS Item Bank v1.0 - Alcohol: Negative Expectancies	
PROMIS Item Bank v1.1 - Anger	PROMIS Anger Item Bank
PROMIS Item Bank v1.0 - Emotional Distress - Anxiety	PROMIS Anxiety Item Bank
PROMIS Item Bank v1.0 - Emotional Distress - Depression	PROMIS Depression Item Bank
PROMIS Item Bank v1.0 - Emotional Distress - Depression (Calibrated Items)	
PROMIS Item Bank v1.0 - Dyspnea Functional Limitations	PROMIS Dyspnea Item Banks
PROMIS Item Bank v1.0 - Dyspnea Severity	
PROMIS Pediatric Item Bank v1.0 - Life Satisfaction- Short Form 8a	PROMIS Pediatric Life Satisfaction Short Forms
PROMIS Pediatric Item Bank v1.0 - Life Satisfaction-Short Form 4a	
PROMIS Pediatric Item Bank v1.0 - Meaning and Purpose- Short Form 8a	PROMIS Pediatric Meaning Purpose Short Forms
PROMIS Pediatric Item Bank v1.0 - Meaning and Purpose-Short Form 4a	

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PROMIS Item Bank or Short Form	New Domain-Specific NOC
PROMIS Item Bank v1.0 - Smoking: Coping Expectancies for All Smokers	PROMIS Smoking Item Banks
PROMIS Item Bank v1.0 - Smoking: Coping Expectancies for Daily Smokers	
PROMIS Item Bank v1.0 - Smoking: Coping Expectancies for Nondaily Smokers	
PROMIS Item Bank v1.0 - Smoking: Emotional and Sensory Expectancies for All Smokers	
PROMIS Item Bank v1.0 - Smoking: Emotional and Sensory Expectancies for Daily Smokers	
PROMIS Item Bank v1.0 - Smoking: Emotional and Sensory Expectancies for Nondaily Smokers	
PROMIS Item Bank v1.0 - Smoking: Negative Health Expectancies for All Smokers	
PROMIS Item Bank v1.0 - Smoking: Negative Health Expectancies for Daily Smokers	
PROMIS Item Bank v1.0 - Smoking: Negative Health Expectancies for Nondaily Smokers	
PROMIS Item Bank v1.0 - Smoking: Negative Psychosocial Expectancies for All Smokers	
PROMIS Item Bank v1.0 - Smoking: Negative Psychosocial Expectancies for Daily Smokers	
PROMIS Item Bank v1.0 - Smoking: Negative Psychosocial Expectancies for Nondaily Smokers	
PROMIS Item Bank v1.0 - Smoking: Nicotine Dependence for All Smokers	
PROMIS Item Bank v1.0 - Smoking: Nicotine Dependence for Daily Smokers	
PROMIS Item Bank v1.0 - Smoking: Nicotine Dependence for Nondaily Smokers	
PROMIS Item Bank v1.0 - Smoking: Social Motivations for All Smokers	
PROMIS Item Bank v1.0 - Smoking: Social Motivations for Daily Smokers	
PROMIS Item Bank v1.0 - Smoking: Social Motivations for Nondaily Smokers	



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## August 2023 Revisions

- The following changes were made to the General Core (F1807) and Demographics (F0016) CRFs:
  - Updated the references links for the following CRF-CDEs to the current NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 defines the minimum standard of basic racial and ethnic categories and FDA Collection of Race and Ethnicity Data in Clinical Trials.
    - F1807: C00020 Ethnicity USA category; C00030 Race USA category
    - F0016: C00020 Ethnicity USA category; C00021 Ethnicity USA paternal category; C00022 Ethnicity USA maternal category; C00030 Race USA category; C00032 Race USA paternal category; C00033 Race USA maternal category
  - F1807: Added the free text 'Other, specify' CDEs for Sex Assigned at Birth and Gender Identity: C58780 and C58781 as Supplemental.
  - F0016: Replaced the previously used Gender Type CDE with the updated Sex Assigned at Birth and Gender Identity CDEs to align with the General Core CRF: C58676/C58780 and C58677/C58781 as Core/Supplemental.

## August 2022 Revisions

- The CDE C00311 Birth weight report value was removed from the Medical History CRF and replaced with CDE C59019 Birth weight measurement. CDE C59019 classified as Supplemental.

## 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.

## April 2015 Revisions

- Released CDEs for the Serious Adverse Events CRF.
- Added the classification 'Supplemental – Highly Recommended' to the glossary and to all disease pages except TBI.
- Inserted additional reference on the 6 Minute Walk Test file.

## March 2015 Revisions

No changes.

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## February 2015 Revisions

- The addition of new standardized disease-specific text explaining that a disease-specific publication related to the CDE development initiative is under development and will be posted to the website as soon as it is available.
- All Start-Up Resource Listings on the website including those for the new diseases were updated to include a link to the Data Standards page for their respective diseases.
- A new glossary image was loaded to the website to include Supplemental-Highly Recommended
- A definition for Supplemental-Highly Recommended was added to the Glossary Index .
- New versions of the NINDS CDE slide sets that include the year 2015 and the new diseases were uploaded to the website on the Meetings and Presentations landing page.
- A new version of the NINDS CDE Project Overview that includes the new diseases was loaded to the website on the Project Overview landing page.

## January 2015 Revisions

No changes.

## November 2014 Revisions

- Changes were made to all Start-Up Resource Listings to include classification definitions, list of the instruments associated with the NIH Resources domain before all others, and list the CDEs that are Core across all diseases.
- Changes were made to all Highlight Summaries to include the instruments associated with the NIH Resources and Suicidal Ideation domains before all others and Domains and Subdomains were added to clearly identify the associated documents listed on the summary.
- The CDEs in use page was updated with new studies in MS, Stroke, PD and TBI.

## September 2014 Revisions

No changes.

## August 2014 Revisions

- CDEs included in new "General Core" CRF now classified as Core for all diseases.
- Updated and corrected versions of various CRFs posted for General.
- History and Acknowledgements updated on General page.
- Links to NeuroQOL, NIH Toolbox, and PROMIS added to all disease website pages.
- Core suicidal ideation instrument, with link, added to all Highlights documents.

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## July 2014 Revisions

- Addition of “NIH Resources” domain, listing the NIH Toolbox, PROMIS, and Neuro-QOL, as the first Domain on every Data Standards tab.

## June 2014 Revisions

No change.

## May 2014 Revisions

No change.

## April 2014 Revisions

No change.

## March 2014 Revisions

No change.

## February 2014 Revisions

No change.

## January 2014 Revisions

- Links to Start-up Resource Listings added to Highlight Summary documents for each disease.

## December 2013 Revisions

- Updated General and Core definitions in glossary.

## November 2013 Revisions

No changes.

## August 2013 Revisions

### Overview

There have been substantial additions of existing data elements to the General CDE materials to allow increased application of these data elements to other disease areas where they would be relevant for data collection. Other changes, since the previous revision release in January 2013, including the following:

## General CDE Revision History Document

### New Forms:

- Godin Leisure-Time Exercise Questionnaire
- Food Frequency Questionnaire (FFQ)
- Risk Factor Questionnaire (RFQ) - NSAIDS and Calcium Channel Blockers (CCB)
- Risk Factor Questionnaire - Occupation and Employment Status (RFQ)
- Risk Factor Questionnaire - Residential History (RFQ)
- Risk Factor Questionnaire-Height and Weight (RFQ-U)
- Risk Factor Questionnaire Pesticides (Home) (RFQ-U)
- Risk Factor Questionnaire- Pesticides (Work) (RFQ-U)
- Risk Factor Questionnaire- Smoking and Tobacco (RFQ-U)
- Glasgow Coma Scale
- Ohio State University TBI Identification Method Short Form
- Grip Strength
- Modified Rankin Scale
- Nine Hole Peg Test
- Timed 25-Foot walk
- Child Behavior Checklist (CBCL)
- Mini International Neuropsychiatric Interview (M.I.N.I.)
- Patient Health Questionnaire-9 (PHQ-9)
- Apathy Scale (AS)
- Brief Psychiatric Rating Scale (BPRS)
- Frontal Systems Behavioral Scale (FrSBe)
- Pittsburgh Sleep Quality Index (PSQI)
- Adaptive Behavior Assessment Scale (ABAS-II)
- Behavior Rating Inventory of Executive Function (BRIEF)

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- Clinical Evaluation of Language Fundamentals
- Grooved Pegboard Test
- Mullen Scales of Early Learning (MSEL)
- Nonverbal Selective Reminding Test (NVSRT)
- Peabody Picture Vocabulary Test 4th Edition (PPVT-4)
- Purdue Pegboard
- Rey Auditory Verbal Learning Test [RAVLT]
- Rey-Osterrieth Complex Figure (ROCF) Copy and Delay
- Vineland Adaptive Behavior Scales, second edition (Vineland-II)
- Wechsler Preschool and Primary Scale of Intelligence (WPPSI-III)
- Epworth Sleepiness Scale (ESS)
- Quantitative Sudomotor Axon Reflex Test (QSART)
- Scale for Outcomes in Parkinson's Disease Sleep (SCOPA-SLEEP)
- Bayley Scales of Infant Development (Bayley III, BSID)
- Pediatric Disability Inventory
- Social Skills Rating Scale
- Test for Executive Control
- 10 Meter Timed Walk
- 6 Minute Walk Test
- Beery-Buktenica Developmental Test of Visual-Motor Integration (Beery VMI)
- Brief Visuospatial Memory Test Revised
- California Verbal Learning Test - Children (CVLT-C)
- California Verbal Learning Test - Second Edition (CVLT-II)
- Comprehensive Test of Phonological Processing (CTOPP)
- Conner's Continuous Performance Test II, Version 5

## General CDE Revision History Document

- Gross Motor Function Measure (GMFM-88, GMFM-66)
- Modified Ashworth Scale
- Pelli Robson Test
- Scale for the Assessment and Rating of Ataxia (SARA)
- Sloan Low Contrast Letter Acuity
- Tardieu Scale
- Test of Memory and Learning (TOMAL-2)
- Wechsler Abbreviated Scale of Intelligence (WASI)
- Wechsler Intelligence Scale For Children (WISC-IV)
- Wide Range Assessment of Memory and Learning (WRAML) - 2 Subtests
- Wisconsin Card Sorting Test (WCST)
- Barthel Index
- Bladder Control Scale (BLCS)
- Bowel Control Scale (BWCS)
- Brief Pain Inventory (BPI)
- Fatigue Severity Scale of Sleep Disorders
- Functional Independence Measure
- Glasgow Outcome Scale (GOS) and Glasgow Outcome Scale - Extended (GOSE)
- Impact of Visual Impairment Scale
- Jebsen-Taylor Hand Functioning Test
- Modified Fatigue Impact Scale
- MOS Pain Effects Scale (PES)
- PROMIS Pain Interference Short Form
- Symbol Digit Modality Test
- Beck Anxiety Inventory (BAI)

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- Beck Depression Inventory (BDI-II)
- Boston Naming Test (BNT) - 30-item version
- Center for Epidemiologic Studies Depression Scale (CES-D)
- Delis Kaplan Executive Functioning System (DKEFS) - Trail Making Tests
- Generalized Anxiety Disorder (GAD-7)
- Geriatric Depression Scale (GDS)
- Hamilton Depression Scale (HDRS)
- Hopkins Verbal Learning Test – Revised (HVLT-R)
- Hospital Anxiety Depression Scale
- Montreal Cognitive Assessment (MoCA)
- Neuropsychiatric Inventory (NPI) Questionnaire
- Phonemic Verbal Fluency
- Stroop Test
- Timed Up and Go
- Wechsler Adult Intelligence Scale (WAIS-IV)
- Woodcock-Johnson Tests of Cognitive Abilities (WJ III NU)
- 36-Item Short Form Health Survey (SF-36)
- Canadian Occupation Performance Measure (COPM)
- Caregiver Burden Scale (CGBS)
- Clinical Global Impression
- EuroQoL-5 Dimension Questionnaire
- EuroQoL VAS
- Healthy Days Core Module (CDC HRQOL-4)
- McGill Pain Questionnaire
- Nottingham Health Profile

## General CDE Revision History Document

- Pediatric Quality of Life Inventory (PEDIQL)
- Quality of Life in Neurological Disorders (Neuro-QOL)
- Quality of Life in Swallowing Disorders (SWAL-QOL)
- Short Form Health Survey-12 (SF-12)
- Sickness Impact Profile

### Updated Forms:

- None

### Removed Forms:

- None

### **Detailed Form Revisions:**

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

#### **1 General Revision History Table**

<b>CRF Module/ Guideline</b>	<b>Current Version</b>	<b>Previous Version</b>	<b>Change Classification</b>	<b>Change Type</b>	<b>Description of Change</b>
Godin Leisure-Time Exercise Questionnaire	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Food Frequency Questionnaire (FFQ)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire (RFQ) - NSAIDS and Calcium Channel Blockers (CCB)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form



## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Risk Factor Questionnaire - Occupation and Employment Status (RFQ)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire - Residential History (RFQ)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire- Height and Weight (RFQ-U)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire Pesticides (Home) (RFQ-U)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire- Pesticides (Work) (RFQ-U)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Risk Factor Questionnaire- Smoking and Tobacco (RFQ-U)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Glasgow Coma Scale	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Ohio State University TBI Identification Method Short Form	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Grip Strength	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Modified Rankin Scale	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Nine Hole Peg Test	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Timed 25-Foot walk	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Child Behavior Checklist (CBCL)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Mini International Neuropsychiatric Interview (M.I.N.I.)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Patient Health Questionnaire-9 (PHQ-9)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Apathy Scale (AS)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Brief Psychiatric Rating Scale (BPRS)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Frontal Systems Behavioral Scale (FrSBe)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Pittsburgh Sleep Quality Index (PSQI)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Adaptive Behavior Assessment Scale (ABAS-II)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Behavior Rating Inventory of Executive Function (BRIEF)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Clinical Evaluation of Language Fundamentals	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Grooved Pegboard Test	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Mullen Scales of Early Learning (MSEL)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Nonverbal Selective Reminding Test (NVSRT)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Peabody Picture Vocabulary Test 4th Edition (PPVT-4)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Purdue Pegboard	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Rey Auditory Verbal Learning Test [RAVLT]	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Rey-Osterrieth Complex Figure (ROCF) Copy and Delay	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Vineland Adaptive Behavior Scales, second edition (Vineland-II)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## General CDE Revision History Document

<b>CRF Module/ Guideline</b>	<b>Current Version</b>	<b>Previous Version</b>	<b>Change Classification</b>	<b>Change Type</b>	<b>Description of Change</b>
Wechsler Preschool and Primary Scale of Intelligence (WPPSI-III)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Epworth Sleepiness Scale (ESS)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Quantitative Sudomotor Axon Reflex Test (QSART)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Scale for Outcomes in Parkinson's Disease Sleep (SCOPA-SLEEP)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Bayley Scales of Infant Development (Bayley III, BSID)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Pediatric Disability Inventory	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Social Skills Rating Scale	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Test for Executive Control	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
10 Meter Timed Walk	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
6 Minute Walk Test	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Beery-Buktenica Developmental Test of Visual- Motor Integration (Beery VMI)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Brief Visuospatial Memory Test Revised	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
California Verbal Learning Test - Children (CVLT-C)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
California Verbal Learning Test - Second Edition (CVLT-II)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Comprehensive Test of Phonological Processing (CTOPP)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Conner's Continuous Performance Test II, Version 5	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Gross Motor Function Measure (GMFM-88, GMFM-66)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Modified Ashworth Scale	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form



## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Pelli Robson Test	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Scale for the Assessment and Rating of Ataxia (SARA)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Sloan Low Contrast Letter Acuity	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Tardieu Scale	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Test of Memory and Learning (TOMAL-2)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Wechsler Abbreviated Scale of Intelligence (WASI)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## General CDE Revision History Document

<b>CRF Module/ Guideline</b>	<b>Current Version</b>	<b>Previous Version</b>	<b>Change Classification</b>	<b>Change Type</b>	<b>Description of Change</b>
Wechsler Intelligence Scale For Children (WISC-IV)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Wide Range Assessment of Memory and Learning (WRAML) - 2 Subtests	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Wisconsin Card Sorting Test (WCST)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Barthel Index	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Bladder Control Scale (BLCS)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Bowel Control Scale (BWCS)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## General CDE Revision History Document

<b>CRF Module/ Guideline</b>	<b>Current Version</b>	<b>Previous Version</b>	<b>Change Classification</b>	<b>Change Type</b>	<b>Description of Change</b>
Brief Pain Inventory (BPI)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Fatigue Severity Scale of Sleep Disorders	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Functional Independence Measure	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Glasgow Outcome Scale (GOS) and Glasgow Outcome Scale - Extended (GOSE)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Impact of Visual Impairment Scale	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Jebsen-Taylor Hand Functioning Test	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Modified Fatigue Impact Scale	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
MOS Pain Effects Scale (PES)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
PROMIS Pain Interference Short Form	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Symbol Digit Modality Test	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Beck Anxiety Inventory (BAI)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Beck Depression Inventory (BDI- II)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## General CDE Revision History Document

<b>CRF Module/ Guideline</b>	<b>Current Version</b>	<b>Previous Version</b>	<b>Change Classification</b>	<b>Change Type</b>	<b>Description of Change</b>
Boston Naming Test (BNT) - 30-item version	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Center for Epidemiologic Studies Depression Scale (CES-D)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Delis Kaplan Executive Functioning System (DKEFS) - Trail Making Tests	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Generalized Anxiety Disorder (GAD-7)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Geriatric Depression Scale (GDS)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Hamilton Depression Scale (HDRS)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## General CDE Revision History Document

<b>CRF Module/ Guideline</b>	<b>Current Version</b>	<b>Previous Version</b>	<b>Change Classification</b>	<b>Change Type</b>	<b>Description of Change</b>
Hopkins Verbal Learning Test – Revised (HVLTR)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Hospital Anxiety Depression Scale	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Montreal Cognitive Assessment (MoCA)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Neuropsychiatric Inventory (NPI) Questionnaire	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Phonemic Verbal Fluency	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Stroop Test	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Timed Up and Go	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Wechsler Adult Intelligence Scale (WAIS-IV)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Woodcock-Johnson Tests of Cognitive Abilities (WJ III NU)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
36-Item Short Form Health Survey (SF-36)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Canadian Occupation Performance Measure (COPM)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Caregiver Burden Scale (CGBS)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

## General CDE Revision History Document

<b>CRF Module/ Guideline</b>	<b>Current Version</b>	<b>Previous Version</b>	<b>Change Classification</b>	<b>Change Type</b>	<b>Description of Change</b>
Clinical Global Impression	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
EuroQoL-5 Dimension Questionnaire	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
EuroQoL VAS	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Healthy Days Core Module (CDC HRQOL-4)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
McGill Pain Questionnaire	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Nottingham Health Profile	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form



## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Pediatric Quality of Life Inventory (PEDSQL)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Quality of Life in Neurological Disorders (Neuro-QOL)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Quality of Life in Swallowing Disorders (SWAL-QOL)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Short Form Health Survey- 12 (SF-12)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Sickness Impact Profile	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

### January 2013 Revisions

#### Overview

There have been substantial additions of existing data elements to the General CDE materials to allow increased application of these data elements to other disease areas where they would be relevant for data collection. Where disease-specific CDEs were identified that had utility to more than one disease, they have been added as Supplemental CDEs for General NINDS CDEs. Other changes, since the previous revision release in June 2012, including the following:

## General CDE Revision History Document

- The footers of all case report form (CRF) modules or “forms” was revised to indicate correct Classification and Version number.
- Changes were made to some General CDEs to reassign their Classification from Core to Supplemental to reduce the number of Core CDEs, in consideration and recognition that some CDEs are not applicable for all study types. The Core CDEs are now a minimum set that should apply to any study of a neurological disorder that receives support from the NINDS.
- The data elements now assigned to General neurological disorders include many CDEs which can be used when Imaging is part of a study.
- The pages for Frontotemporal Dementia (FTD) were removed from the NINDS CDE website. Existing dementia CDEs that are used in Amyotrophic Lateral Sclerosis studies will be maintained. For more information on FTD, please visit the National Institute on Aging (NIA) (<http://www.nia.nih.gov/>) or the Association for Frontotemporal Degeneration (AFTD) ([Please click here for the Association for Frontotemporal Degeneration](#)).

### Form Status Changes

#### New Forms:

- Supplemental Demographics Data Elements
- Supplemental Social Status Data Elements
- Supplemental Health History
- Supplemental Epidemiology or Environmental History Data Elements
- Supplemental History of Disease or Injury Event Data Elements
- Supplemental Classification Data Elements
- Supplemental Second Insults Data Elements
- Supplemental Discharge Data Elements
- Supplemental Physical/Neurological Examination Data Elements
- Supplemental Vital Signs and Other Body Measures Data Elements
- Supplemental Laboratory Tests and Biospecimens/Biomarkers Data Elements
- General Imaging Diagnostics
- Supplemental Drugs Data Elements

## General CDE Revision History Document

- Supplemental Surgeries and Other Procedures Data Elements
- Supplemental Therapies Data Elements
- Supplemental Enrollment Data Elements
- Supplemental Other Clinical Data Data Elements

### **Updated Forms:**

- Demographics
- Social Status
- Medical History
- Family History
- Behavioral History
- Physical Exam
- Vital Signs
- Laboratory Tests and Tracking
- Electrocardiogram (ECG)
- Prior and Concomitant Medications
- Study Drug Dosing
- Study Drug Compliance
- Study Therapies Compliance
- Screening Log
- Inclusion and Exclusion Criteria
- Informed Consent and Enrollment
- Protocol Deviations
- Study Discontinuation/Completion
- Participant/Subject Contact Information
- Visit Checklist

## General CDE Revision History Document

- Visit Schedule
- Adverse Events
- Serious Adverse Events
- Death Report

**Removed Forms:**

- None

**Detailed Form Revisions:**

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

**2 General CDE Revision History Table**

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
All	Varies	Varies	Minor	Modified Forms	CDE instructions were updated on this form to indicate data elements that are Core.
All	Varies	Varies	Minor	Modified CDEs	Selected CDEs were changed from Core to Supplemental at direction from NINDS, based on considerations of broad types of studies supported by NINDS investigators.
All	Varies	Varies	Minor	Modified CDEs	Selected CDEs were modified to correct typographical errors or minor changes to naming or definitions to provide clarity or improve association to related CDEs.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Supplemental Demographics Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional Demographics CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.
Supplemental Demographics Data Elements	1.0	N/A - new form	Minor	New CDEs	A new CDE was created for participant/subject demographics to allow both Gender and Sex to be collected as needed. The new CDEs include: Sex participant or subject type.
Supplemental Social Status Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional Social Status CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Supplemental Health History	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional General Health History CDEs. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.
Supplemental Epidemiology or Environmental History Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional Epidemiology/Environmental History CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Supplemental History of Disease or Injury Event Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional History of Disease/Injury Event CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.
Supplemental Classification Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional Classification CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Supplemental Second Insults Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional Second Insults CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.
Supplemental Discharge Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional Discharge CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.



## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Supplemental Physical/Neurological Examination Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional Physical and Neurological Examination CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.
Supplemental Vital Signs and Other Body Measures Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional Vital Signs and Body Measures CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Supplemental Laboratory Tests and Biospecimens/Biomarkers Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional Laboratory Tests and Biospecimens/Biomarkers CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.
General Imaging Diagnostics	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide Imaging Diagnostics CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Supplemental Drugs Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional Medication and Study Drug CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.
Supplemental Surgeries and Other Procedures Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional Surgeries and Other Procedures CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Supplemental Therapies Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional Therapies CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.
Supplemental Enrollment Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional Participant/Subject Enrollment CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.
Supplemental Enrollment Data Elements	1.0	N/A - new form	Minor	New CDEs	Six new CDEs were created for administrative use for database and protocol management, which include: Site Name, Site Number, Visit Date, Visit Type, Visit Number, and GUID.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Supplemental Other Clinical Data Data Elements	1.0	N/A - new form	Major	New form	This CRF was created using existing CDEs to provide additional Clinical Data CDEs to General. The data elements can be used for any study where they are needed to collect study data, but are all Supplemental. There is CRF document to graphically represent this CRF. Steering Committee recommendations have not been given for these CDEs at this time.
N/A	---	---	Major	Deleted pages	The pages for Frontotemporal Dementia (FTD) were removed from the NINDS CDE website. Existing dementia CDEs that are used in Amyotrophic Lateral Sclerosis studies will be maintained on the website under ALS. For more information on FTD, please visit the National Institute on Aging (NIA) ( <a href="http://www.nia.nih.gov/">http://www.nia.nih.gov/</a> ) or the Association for Frontotemporal Degeneration (AFTD) ( <a href="http://www.ftd-picks.org/">http://www.ftd-picks.org/</a> ).

### June 2012 Revisions

#### Overview

There have been significant changes to the content and structure of the General CDE materials since the previous revision release in February 2011 including the following:

Every attempt was made to remove duplication and redundancy in the General CDEs;

## General CDE Revision History Document

The General CDEs were harmonized with other large national and international standardization initiatives and efforts [e.g., International Conference on Harmonisation (ICH), Logical Observation Identifiers Names and Codes (LOINC), International Classification of Diseases (ICD), Unified Code for Units of Measure (UCUM)]

- The majority of element names and definitions were improved.
- The permissible values and references of some elements were revised; and
- The version numbers of all forms were updated.

The corresponding data dictionaries (i.e., CDE Detailed Report) and instructions have been modified in accordance with the form changes.

### Form Status Changes

#### New Forms:

- Social Status

#### Modified Forms:

- Demographics
- Medical History
- Family History
- Behavioral History
- Physical Exam
- Vital Signs
- Laboratory Tests and Tracking
- Electrocardiogram (ECG)
- Prior and Concomitant Medications
- Study Drug Dosing
- Study Drug Compliance
- Study Therapies Compliance
- Inclusion and Exclusion Criteria

## General CDE Revision History Document

- Informed Consent and Enrollment
- Protocol Deviations
- Study Discontinuation/Completion
- Adverse Events
- Death Report

**Removed Forms:**

- None

**Detailed Form Revisions:**

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

**3 General CDE Revision History Table**

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
All	Varies	Varies	Minor	Modified CDEs	Nearly all CDE names and definitions were updated to achieve greater internal consistency.
All	Varies	Varies	Minor	Modified CDEs	Date, Time, and Time type value CDEs capturing a single point in time were merged into one Date and Time element. For example, Date of Birth, Time of Birth, and Time Type Value became Date and time of Birth. The instructions for date and time elements specify that the data should be recorded to the level of detail known.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
All	Varies	Varies	Minor	Modified CDEs	CDEs that allowed free text to specify an answer of "Other" were merged into the preceding element. For example, "Family medical history condition other specify" was deleted and "Family history medical condition type" was given a permissible value for "Other, specify".
Demographics	4.1	4.0	Minor	Modified form	The following CDEs were moved from the form to another form: Marital or partner status; Hand preference type; Education level USA type; Birth weight value; Gestational age value; Postnatal age value; Post conceptional age value; Head circumference measurement; Head circumference unit of measure; APGAR five minute score; APGAR ten minute score
Demographics	4.1	4.0	Minor	Modified form	The following CDEs were relabeled on the form: Gender (formerly called Sex)
Demographics	4.1	4.0	Minor	Modified CDEs	The following CDE instructions were updated: Gender type; Birth date and time; Race USA category; Ethnicity USA category; Race USA maternal category; Race USA paternal category



## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Social Status	1.1	N/A - new form	Minor	New form	The Social Status CRF was created with existing CDEs (Marital/Partner status and Education level USA type) originally on the Demographics CRF.
Social Status	1.1	N/A - new form	Minor	Modified CDEs	The following CDE permissible values were updated: Marital or Partner Status.
Social Status	1.1	N/A - new form	Minor	Modified CDEs	The following CDE instructions were updated: Marital or Partner Status; Education level USA type.
Medical History	4.1	4.0	Major	Modified CDEs	The permissible values for the following CDE were updated: Body system category.
Medical History	4.1	4.0	Minor	Modified form	The following CDEs were relabeled on the form: Medical history condition ongoing indicator
Medical History	4.1	4.0	Minor	Modified form	The following CDEs were added to the form: Birth weight value; Gestational age value; Postnatal age value; Post conceptional age value; APGAR five minute score; APGAR ten minute score. These CDEs used to be included on the Demographics CRF.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Medical History	4.1	4.0	Minor	Modified CDEs	The following CDE instructions were updated: Medical history taken date and time; Medical history global assessment indicator; Body system category; Medical history condition text; Medical history condition start date and time; Medical history condition end date and time; Birth weight value; Gestational age value; Postnatal age value; Post conceptual age value; APGAR five minute score; APGAR ten minute score
Medical History	4.1	4.0	Major	New CDEs	The following CDE was added: Medical History Condition SNOMED CT Code. This CDE does not appear on the CRF, though it is included in the Data Dictionary, as it is likely the condition will be coded on the backend.
Medical History	4.1	4.0	Minor	Deleted CDEs	The following CDEs were deleted: Other body system
Family History	4.1	4.0	Major	Modified CDEs	The permissible values for the following CDEs were updated: Family history medical condition type; Family history medical condition indicator; Family history medical condition relative type.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Family History	4.1	4.0	Minor	Modified CDEs	The following CDE instructions were updated: Family history medical condition type; Family history medical condition indicator; Family history medical condition relative type
Behavioral History	4.1	4.0	Minor	Modified CDEs	All CDE instructions (including skip patterns) were updated
Behavioral History	4.1	4.0	Minor	Modified form	The following CDEs were relabeled on the form: Tobacco current use indicator; Tobacco prior use indicator; Tobacco use started age value; Tobacco use stopped age value; Tobacco cigarettes smoked daily; Alcohol prior use indicator; Alcohol consume six or more drinks frequency.
Behavioral History	4.1	4.0	Major	New CDEs	The following CDE was added: Tobacco product used type.
Behavioral History	4.1	4.0	Major	Deleted CDEs	The following CDE was deleted: Current/past regular use of cigars, pipes, or chewing tobacco.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Behavioral History	4.1	4.0	Major	Modified CDEs	The permissible values for the following CDEs were modified: Tobacco cigarettes smoked daily average number; Alcohol use frequency; Alcohol drinking day average drinks consumed; Alcohol consume six or more drinks frequency; Drug or substance illicitly used category.
Physical Exam	3.1	3.0	Minor	Modified form	The following CDE was added to this form: Hand preference type. This CDE used to be on the Demographics CRF.
Physical Exam	3.1	3.0	Major	New CDEs	The following CDE was added: Physical exam condition SNOMED CT code. This CDE does not appear on the CRF, though it is included in the Data Dictionary, as it is likely the condition will be coded on the backend.
Physical Exam	3.1	3.0	Major	Modified CDEs	The permissible values for the following CDEs were updated: Body system category; Physical exam body system result; Physical exam abnormality significance type; Hand preference type.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Physical Exam	3.1	3.0	Minor	Modified CDEs	The following CDE instructions were updated: Body system category; Physical exam date and time; Physical exam performed indicator; Physical exam body system result; Physical exam abnormality significance type; Hand preference type.
Physical Exam	3.1	3.0	Minor	Deleted CDEs	The following CDE was deleted: Other Body System.
Laboratory Tests and Tracking	3.1	3.0	Minor	Modified CDEs	The instructions for the following CDEs were updated: Lab specimen collection date and time; Lab test performed indicator; Lab test result; Lab test result status; Lab test abnormality significance type.
Laboratory Tests and Tracking	3.1	3.0	Major	Modified CDEs	The permissible values for the following CDEs were updated: Lab test name; Lab test result status; Lab test abnormality significance type.
Laboratory Tests and Tracking	3.1	3.0	Major	New CDEs	The following CDEs were added: Lab test LOINC code; Lab test result unit of measure UCUM code. These CDEs do not appear on the CRF, though they are included in the Data Dictionary, as it is likely they will be coded on the backend.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Laboratory Tests and Tracking	3.1	3.0	Minor	Modified form	The following change was made to the form: Lab test performed indicator was moved into the chart of test results.
Vital Signs	3.1	3.0	Major	Modified CDEs	The permissible values for the following CDE was updated: Temperature measurement anatomic site.
Vital Signs	3.1	3.0	Minor	Modified form	The following CDEs were added to this form: Head circumference measurement; Head circumference unit of measure. These two CDEs used to be on the Demographics CRF.
Vital Signs	3.1	3.0	Minor	Modified CDEs	The following CDE instructions were updated: Vital signs date and time; Blood pressure systolic measurement; Blood pressure diastolic measurement; Blood pressure measurement position type; Temperature measurement anatomic site; Height measurement
Vital Signs	3.1	3.0	Minor	Modified form	The instructions for the following CDEs were added to the form: Temperature unit of measure; Weight unit of measure; Height unit of measure.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Electrocardiogram	2.1	2.0	Major	Modified CDEs	The permissible values for the following CDEs were updated: ECG heart rhythm result; ECG atrial arrhythmia type; ECG ventricular arrhythmia type.
Electrocardiogram	2.1	2.0	Minor	Modified form	The following CDEs were relabeled on form: ECG atrial arrhythmia type; ECG ventricular arrhythmia type.
Electrocardiogram	2.1	2.0	Minor	Modified CDEs	The following CDE instructions were updated: ECG assessment date and time; ECG heart rate; ECG PR interval; ECG QRS duration; ECG QT interval; ECG QTc interval; ECG atrial arrhythmia type; ECG ventricular arrhythmia type; ECG ST segment abnormality indicator; ECG T wave abnormality indicator; ECG right ventricular hypertrophy indicator; ECG left ventricular hypertrophy indicator; ECG previous myocardial infarction indicator; ECG complete bundle branch block indicator.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Protocol Deviations	4.1	4.0	Minor	Modified CDEs	The following CDE instructions were modified: Protocol deviation occurrence indicator; Protocol deviation description text; Protocol deviation occurrence date and time.
Study Therapies Compliance	1.1	1.0	Minor	Modified CDEs	The instructions for the following CDE were updated: Study therapy administered date and time.
Study Therapies Compliance	1.1	1.0	Minor	Modified Form	The following CDE was relabeled on the form: Study therapy administered date and time.
Study Therapies Compliance	1.1	1.0	Major	Deleted CDEs	The following CDEs were deleted: Study therapy source; Study therapy comments.
Prior and Concomitant Medications	4.1	4.0	Major	New CDEs	The following CDEs were added: Medication prior or concomitant RXNorm code; Medication prior or concomitant dose unit of measure UCUM code. These CDEs do not appear on the CRF, though they are included in the Data Dictionary, as it is likely they will be coded on the backend.



## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Prior and Concomitant Medications	4.1	4.0	Major	Modified CDEs	The permissible values for the following CDEs were modified: Medication prior or concomitant dose frequency; Medication prior or concomitant route type; Medication prior or concomitant dose unit of measure.
Prior and Concomitant Medications	4.1	4.0	Minor	Modified CDEs	The CDE instructions were modified for all CDEs on this form.
Prior and Concomitant Medications	4.1	4.0	Minor	Modified form	The following CDE was relabeled on the form: Medication prior or concomitant ongoing indicator.
Study Drug Dosing	3.1	3.0	Minor	Modified CDEs	The instructions for the following CDEs were updated: Study drug start date and time; Study drug end date and time; Study drug unit of measure; Study drug unit of measure UCUM code; Study drug dose frequency.
Study Drug Dosing	3.1	3.0	Major	New CDEs	The following CDE was added: Study drug dose unit of measure UCUM code. This CDE does not appear on the CRF, though it is included in the Data Dictionary, as it is likely the condition will be coded on the backend.
Study Drug Dosing	3.1	3.0	Major	Modified CDEs	The permissible values for the following CDEs were updated: Study drug dose unit of measure; Study drug dose frequency.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Adverse Events	4.1	4.0	Major	New CDEs	The following CDEs were added: Adverse event CTCAE low level term name; Adverse event MedDRA lower level term code. These CDEs do not appear on the CRF, though they are included in the Data Dictionary, as it is likely they will be coded on the backend.
Adverse Events	4.1	4.0	Minor	Modified CDEs	The permissible values for the following CDE were modified: Adverse event severity scale.
Adverse Events	4.1	4.0	Minor	Modified CDEs	The instructions for the following CDEs were updated: Adverse event during study indicator; Adverse event start date and time; Adverse event end date and time; Adverse event severity scale; Adverse event relatedness scale; Adverse event study intervention action taken type; Adverse event other action taken type; Adverse event outcome status; Serious adverse event indicator.
Study Drug Compliance	2.1	2.0	Minor	Modified CDEs	The instructions for the following CDEs were updated: Study drug dosage form type; Study drug dispensed date and time; Study drug returned date and time.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Study discontinuation/completion	4.1	4.0	Minor	Modified form	The following CDE was relabeled on the form: Off study date and time.
Study discontinuation/completion	4.1	4.0	Minor	Modified form	The permissible values for the 'Off study intervention prematurely reason' CDE were reordered on the form.
Study discontinuation/completion	4.1	4.0	Major	Modified CDEs	The permissible values for the following CDE were updated: Off study reason.
Study discontinuation/completion	4.1	4.0	Minor	Modified CDEs	All CDE instructions were updated on this form.
Informed Consent and Enrollment	2.1	2.0	Major	Deleted CDEs	The following CDE was deleted: Date assent form given.
Informed Consent and Enrollment	2.1	2.0	Minor	Modified form	All CDE instructions were updated on this form.
Death report	3.1	3.0	Minor	Modified CDEs	The instructions for the following CDE were updated: Death cause text; Death cause ICD-9-CM code.
Death report	3.1	3.0	Major	Deleted CDEs	The following CDEs were deleted: Primary cause of death.
Death report	3.1	3.0	Minor	Modified form	The following CDEs were relabeled on the form: Death cause ICD-9-CM code; Death cause text.

# General CDE Revision History Document

## February 2011 Revisions

### Overview

There have been significant changes to the content and structure of the General CDE materials since the previous revision release in November 2008 including the following:

- The header of all case report form (CRF) modules or “forms” was revised;
- The version number of all forms was updated;
- 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 February 2011 revisions, the NINDS CDE Team worked to harmonize the General CDEs with the National Cancer Institute’s caBIG (cancer Biomedical Informatics Grid) CDE Standards. Many of the form and CDE revisions incorporated into the February 2011 revision release resulted from this harmonization work.

### Form Status Changes

#### New Forms:

- Study Therapies Compliance

#### Modified Forms:

- Demographics
- Medical History (Previously called: Medical History – Review of Systems at Baseline)
- Family History (Previously called: Family History at Baseline)
- Behavioral History (Previously called: Behavioral History at Baseline)
  - Harmonized General CDE Behavioral History with the Stroke CDE Behavioral History
- Physical Exam
- Vital Signs (Previously called: Vital Signs, Weight and Height)
- Laboratory Tests and Tracking

## General CDE Revision History Document

"Laboratory Tests" and "Laboratory Tracking" were combined into one form called "Laboratory Tests and Tracking"

- Electrocardiogram (ECG)
  - Harmonized General CDE ECG with the Stroke CDE ECG
- Prior and Concomitant Medications
- Study Drug Dosing
- Study Drug Compliance
- Inclusion and Exclusion Criteria
- Informed Consent and Enrollment
- Protocol Deviations
- Study Discontinuation/Completion
- Adverse Events
- Death Report

### **Removed Forms:**

- Surgical History at Baseline
  - Past surgeries will be recorded on the Medical History form
- Trail Making
  - Can be found in Stroke CDEs
- Modified Rankin Scale
  - Can be found in Stroke CDEs

### **Detailed Form Revisions:**

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

## General CDE Revision History Document

4 General CDE Revision History Table

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Demographics	4.0	3.0	Major	New CDEs	The following CDEs were added: Marital/Partner Status; Handedness; Time of Birth; Time Type Value; Birth Weight; Gestational Age; Post Natal Age (PNA); Post Conceptional Age (PCA); Head Circumference; Head Circumference Unit; 5 Minute APGAR Score; 10 Minute APGAR Score; Maternal Ethnicity; Maternal Race; Paternal/Ethnicity; and Paternal Race.
Demographics	4.0	3.0	Major	Modified CDEs	The permissible values/codes For the following CDEs were modified: Sex; Ethnicity; Racial Category; and Education Level.
Medical History	4.0	3.0	Major	Deleted CDEs	The following CDE was deleted: Sequence Number for Medical History Condition
Medical History	4.0	3.0	Major	New CDEs	The following CDEs were added: Event Occurrence Date; Ongoing Indicator; End Date; Date Medical History Taken; and Other Body System
Medical History	4.0	3.0	Major	Modified CDEs	The permissible values/codes for the following CDE were modified: Body System
Medical History	4.0	3.0	Minor	Modified Form	The title and layout of the form were modified.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Family History	4.0	3.0	Major	Deleted CDEs	The following CDE was deleted: Sequence Number for Family History Record
Family History	4.0	3.0	Major	Modified CDEs	The permissible values/codes for the following CDEs were modified: Condition; Occurrence Indicator; and Relative Type
Family History	4.0	3.0	Minor	Modified Form	The CRF title was revised and the layout was condensed to minimize the data entry burden.
Behavioral History	4.0	3.0	Major	Deleted CDEs	The following CDEs were deleted: Cigarettes Smoked for One Year; Years of Cigarette Smoking; Unit for Average Quantity of Cigarettes Smoked; Years of Cigar/Pipe Smoking; Average Quantity of Cigars/Pipes Smoked; Unit for Average Quantity of Cigars/Pipes Smoked; Chewing Tobacco/Snuff Used for One Year; Years of Chewing Tobacco/Snuff Use; Average Quantity of Chewing Tobacco/Snuff Used; Unit for Average Quantity of Chewing Tobacco/Snuff Used; and Years of Alcohol Consumption

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Behavioral History	4.0	3.0	Major	New CDEs	The following CDEs were added: Assessment Date; Past Habit of Smoking Cigarettes but not in Last Year; Age Started Smoking in Years; Age Quit Smoking in Years; Age Started Drinking; Age Quit Drinking; Alcohol Use Five or More Drinks Frequency; Alcohol Use Related Hospitalization; Current Drug User Indicator; Types of Illicit Drugs Used; and Other Types of Illicit Drugs Used
Behavioral History	4.0	3.0	Major	Modified CDEs	The permissible values/codes for the following CDEs were modified: Current Smoker Indicator; Average Packs Smoked per Day; Current/Past Regular Use of Cigars, Pipe, or Chewing Tobacco Indicator; Alcohol Current Use Indicator; Past Consumption of Alcohol but not in Last Year; Alcohol Use Frequency; and Alcohol Drinks per Day
Behavioral History	4.0	3.0	Minor	Modified Form	The CRF title was revised and a cartoon to illustrate alcoholic drink serving size was added.



## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Physical Exam	3.0	2.0	Major	Deleted CDEs	The following CDEs were deleted: Physical Exam Finding Sequence Number; and Abnormal Finding
Physical Exam	3.0	2.0	Major	New CDEs	The following CDEs were added: Date the Physical Exam was Performed; Body System; Finding Status; Other Body System; and Physical Exam Clinical Significance Abnormal Flag
Physical Exam	3.0	2.0	Minor	Modified Form	The CRF format was modified to increase standardization by minimizing free text fields.
Vital Signs	4.0	3.0	Major	New CDEs	The following CDEs were added: Respiratory Rate; Position of Blood Pressure Measurement; and Temperature Method
Vital Signs	4.0	3.0	Minor	Modified Form	The CRF title was revised.

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Laboratory Tests and Tracking	3.0	2.0	Major	Deleted CDEs	The following CDE was deleted: Comments (as previously found on Version 2.0 Laboratory Tracking)
Laboratory Tests and Tracking	3.0	2.0	Major	New CDEs	The following CDEs were added: Lab Panel; Lab Panel Other; Sample Collection Date; Sample Collection Time; Time Type Value; Specimen Accession Number; Test Results Reported; Test Result Abnormal Flag; and Result Clinical Significance Abnormal Flag
Laboratory Tests and Tracking	3.0	2.0	Major	Modified Form	This form has been compiled from the previous versions of "Laboratory Tests" and "Laboratory Tracking" in order to condense the information onto one form.
Electrocardiogram (ECG)	2.0	1.0	Major	Deleted CDEs	The following CDEs were deleted: Conduction; Axis; Abnormal U Waves; Corrected QT interval; Prolonged QTcB Measurement; Other Abnormality; and Other Abnormality Specification

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Electrocardiogram (ECG)	2.0	1.0	Major	New CDEs	The following CDEs were added: Atrial Arrhythmia; Ventricular Arrhythmia; and Patterns of Complete Bundle Branch Block
Electrocardiogram (ECG)	2.0	1.0	Major	Modified CDEs	The permissible values/codes for the following CDEs were modified: Heart Rhythm; ST Segment Abnormality; T Wave Abnormality; Right Ventricular Hypertrophy; Left Ventricular Hypertrophy; and Patterns of Previous Myocardial Infarction
Prior and Concomitant Medications	4.0	3.0	Major	Deleted CDEs	The following CDE was deleted: Sequence Number
Prior and Concomitant Medications	4.0	3.0	Major	New CDEs	The following CDEs were added: Dose; Dose Unit; Dose Unit Other; Dose Frequency; Dose Frequency Other; Route; Route Other; Start Time; Time Type Value; and End Time

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Prior and Concomitant Medications	4.0	3.0	Major	Modified CDEs	The permissible values/codes for the following CDE were modified: Administration Continue Indicator
Study Drug Dosing	3.0	2.1	Major	Deleted CDEs	The following CDE was deleted: Sequence Number for Study Drug Dosing Record
Study Drug Dosing	3.0	2.1	Major	New CDEs	The following CDEs were added: Dose Unit Other; and Dose Frequency Other
Study Drug Dosing	3.0	2.1	Major	Modified CDEs	The permissible values/codes for the following CDEs were modified: Dose Unit; and Dose Frequency
Study Drug Compliance	2.0	1.1	Major	Deleted CDEs	The following CDE was deleted: Sequence Number for Study Drug Compliance Record

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Study Drug Compliance	2.0	1.1	Major	New CDEs	The following CDE was added: Expected Amount Taken
Study Drug Compliance	2.0	1.1	Minor	Modified CDEs	The name of the following CDE was revised but the permissible values remain the same: Dose Form
Informed Consent and Enrollment	2.0	1.0	Major	Modified CDEs	The permissible values/codes for the following CDEs were modified: Yes/No Indicator whether the Informed Consent Form was Signed; Yes or No Indicator to Specify that a Participant/Subject has been Randomized
Study Discontinuation/Completion	4.0	3.1	Major	Deleted CDEs	The following CDEs were deleted: Death Report Form Completed; and Adverse Event Form Completed

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Study Discontinuation/Completion	4.0	3.1	Major	Modified CDEs	The permissible values/codes for the following CDE were modified: Off Intervention Reason
Adverse Events	4.0	3.0	Major	Deleted CDEs	The following CDE was deleted: AE Sequence Number
Adverse Events	4.0	3.0	Major	New CDEs	The following CDEs were added: Start Time; End Time; Time Type Value; Action Taken with Study Intervention; and Other Action Taken
Adverse Events	4.0	3.0	Major	Modified CDEs	The permissible values/codes for the following CDEs were modified: Severity; Relatedness; and Outcome
Death Report	3.0	2.0	Major	New CDEs	The following CDEs were added: ICD-10 Code for Primary Cause of Death; Primary Death Reason Other Specify; and Official Cause of Death

## General CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Death Report	3.0	2.0	Major	Modified CDEs	The permissible values/codes for the following CDE were modified: Primary Cause of Death