

Spinal Cord Injury CDE Revision History Document

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June 2020 Revisions

- Outcome measures added to the Spinal Cord Injury (SCI) Data Standards page:
 - Epworth Sleepiness Scale – Children and Adolescents (ESS-CHAD), Classification: Supplemental
 - Spinal Cord Ability Ruler, Classification: Exploratory
 - The Mini-Balance Evaluation Systems Test (Mini-BESTest), Classification: Exploratory
- Outcome measures removed from the SCI Data Standards page:
 - Tetraplegia Hand Activity Questionnaire (THAQ)
 - The Activities Based Balance Level Evaluation (ABLE) Scale
 - Berlin Questionnaire
 - Functional Outcomes of Sleep Questionnaire (FOSQ)
 - Infant Sleep Questionnaire
 - Obstructed Sleep Apnea-18 (OSA-18)
- Recommendations for Use added for Supplemental – Highly Recommended classification:
 - 10 Meter Timed Walk
 - 2 Minute Walk Test
 - 6-Minute Walk Test
 - Spinal Cord Independence Measure, Spinal Cord Injury Functional Index / Assistive Technology (SCI-FI/AT)
 - Patient Health Questionnaire - 9 (PHQ-9) Depression Scale
 - Qualiveen
- Classifications upgraded from Exploratory to Supplemental:
 - Graded Redefined Assessment of Strength, Sensibility and Prehension (GRASSP)
 - Spinal Cord Injury Functional Ambulation Inventory (SCI-FAI)
 - Capabilities Upper Extremity Test (CUE-T)
 - Douleur Neuropathique 4 (DN4)
 - Neuropathic Pain Symptom Inventory (NPSI)
 - PainDETECT
- Classifications upgraded from Exploratory to Supplemental for SCI-Pediatric:
 - Capabilities Upper Extremity Test (CUE-T)
 - Segmental Assessment of Trunk Control (SATCo)
 - Spinal Cord Injury Functional Ambulation Inventory (SCI-FAI)
- Classifications upgraded from Supplemental to Supplemental – Highly Recommended for Spinal Cord Injury:
 - 2 Minute Walk Test
 - Qualiveen
- Classification downgraded from Supplemental – Highly Recommended to Supplemental:
 - Epworth Sleepiness Scale (ESS) – Adult Version

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- Classifications downgraded from Supplemental – Highly Recommended to Supplemental for SCI-Pediatric:
 - Pediatric Evaluation of Disability Inventory (PEDI)
 - Epworth Sleepiness Scale–Children and Adolescents (ESS-CHAD)
- Classifications downgraded from Supplemental to Exploratory for SCI-Pediatric:
 - Tayside Children’s Sleep Questionnaire (TCSQ)
 - Adolescent Pediatric Pain Tool (APPT)
 - Children’s Activity Limitations Interview (CALI)
 - Adolescent Sleep Hygiene Scale Revised (ASHSr)
 - Adolescent Sleep Wake Scale (ASWS)
 - Brief Infant Sleep Questionnaire (BISQ),
 - Children’s Sleep Habits Questionnaire (CSHQ) – Preschool and School Age
- International Standards for Neurological Classification of SCI Worksheet was updated to latest version 04/2019
- Titles revisions:
 - Pediatric Spinal Cord Injury Activity Measure (PEDI-SCI AM) revised to Pediatric Spinal Cord Injury Activity Measure (PEDI-SCI AM) Short Forms
 - Spinal Cord Independence Measure (SCIM) – III Self Report for Youth revised to Spinal Cord Independence Measure (SCIM) – III for Youth
 - Spinal Cord Injury Functional Index (SCI-FI) revised to Spinal Cord Injury Functional Index / Assistive Technology (SCI-FI/AT)
 - Adolescent Sleep Hygiene Scale revised to Adolescent Sleep Hygiene Scale Revised (ASHSr)
 - Epworth Sleepiness Scale (ESS) – Children Version revised to Epworth Sleepiness Scale–Children and Adolescents (ESS-CHAD)
- Berg Balance Scale (BBS): Classification downgraded from Supplemental – Highly Recommended to Supplemental; not recommended for youth <18y Fatigue Severity Scale (FSS): Classification revised for SCI and SCI-Pediatric: Supplemental: SCI and SCI-Pediatric for adolescents 16 years or older
- Spinal Cord Injury Functional Index / Assistive Technology (SCI-FI/AT): Classifications upgraded from Exploratory to Supplemental – Highly Recommended for Spinal Cord Injury and revised for Spinal Cord Injury – Pediatric from Supplemental: SCI-Pediatric (not recommended for < 18) to Supplemental: SCI-Pediatric (not recommended for < 16)
- World Health Organization Quality of Life Assessment (WHOQOL-BREF): Classification for SCI-Pediatric revised from Supplemental Spinal Cord Injury (SCI) to Supplemental: Spinal Cord Injury (SCI), SCI-Pediatric (16 years of age and older)

January 2020 Revisions

- General Core CRF updated to replace 'Gender' question with 'Sex assigned at birth' and 'Gender identity'.

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- 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.

June 2017 Revisions

- Female and Male Sexual and Reproductive Function Basic Data Sets v2.0 posted

May 2017 Revisions

- Core Basic Data Set v2.0 posted

March 2017 Revisions

- Bowel Basic Data Set v2.0 posted
- Pediatric SCI publication added to SCI References: Mulcahey MJ, Vogel LC, Sheikh M, Arango-Lasprilla JC, Augutis M, Garner E, Hagen EM, Jakeman LB, Kelly E, Martin R, Odenkirchen J, Scheel-Sailer A, Schottler J, Taylor H, Thielen CC, Zebracki K. Recommendations for the National Institute for Neurologic Disorders and Stroke spinal cord injury common data elements for children and youth with SCI. Spinal Cord. 2016 Nov 15. PubMed PMID: 27845358.

February 2017 Revisions

- Fracture History Extended Data Set v1.0 link added to website

December 2016 Revisions

- SCI Oversight Committee revisions posted (See table for summary of revisions):

Document	Comments
General Core	CRF updated
Demographics	CRF and CDEs updated
Medical History	CRF and CDEs updated; ISCoS Data Set instructions and references added
Prior and Concomitant Medications	CRF and CDEs updated; ISCoS Data Set instructions and references added
Alcohol and Tobacco Use	CRF and CDEs updated; ISCoS Data Set instructions and references added

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Document	Comments
Substance Use	CRF and CDEs updated
History of Injury	CRF and CDEs updated; ISCoS Data Set instructions and references added
Pre-Hospital Assessment	CRF and CDEs updated; ISCoS Data Set instructions and references added
Acute Admission/Discharge	CRF and CDEs updated
Adverse Events	CRF and CDEs updated
Rehabilitation Admission/Discharge	CRF and CDEs updated; ISCoS Data Set instructions and references added
Clinical Assessment	CRF and CDEs updated; ISCoS Data Set instructions and references added
Physical Exam	CRF and CDEs updated; ISCoS Data Set instructions and references added
Vital Signs and Tests	CRF and CDEs updated; ISCoS Data Set instructions and references added
Laboratory Tests	CRF and CDEs updated
Magnetic Resonance Imaging	CRF updated
Rehabilitation Therapies	CRF and CDEs updated
Surgical and Procedural Interventions	CRF and CDEs updated; ISCoS Data Set instructions and references added
Other Investigational Treatments	CRF updated
International Standards for Neurological Classification of SCI Worksheet (ISNCSCI)	CRF updated to 2015 ASIA version; reference updated
Algorithm for Using SCI Electrodiagnostic CDEs	CRF updated

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Document	Comments
2 Minute Walk Test NOC	NOC updated
Capabilities Upper Extremity Questionnaire NOC	NOC updated
Capabilities Upper Extremity Test NOC	NOC updated
Five Times Sit to Stand Test NOC	NOC updated; classification revised to Supplemental
Grasp and Release Test NOC	NOC updated
Sollerman Hand Function Test NOC	NOC updated
SCI Functional Ambulation Inventory NOC	NOC updated
SCI Functional Index NOC	NOC updated
Stair Climb Guidelines	NOC updated
Timed Up and Go NOC	NOC updated
Toronto Rehabilitation Institute Hand Function Test NOC	NOC updated
Walking Index SCI NOC	NOC updated
Wheelchair Circuit NOC	NOC updated
Wheelchair Skills Test NOC	NOC updated
International SCI Pain Basic Data Subset	CRF and CDEs updated
Multidimensional Pain Inventory Pain Severity Subscale NOC	NOC updated

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Document	Comments
Neuropathic Pain Symptom Inventory NOC	NOC updated
PainDETECT NOC	NOC updated
Euro-QoL 5 Dimension Questionnaire NOC	NOC updated
Life Satisfaction Questionnaire NOC	NOC updated
Quality of Life Index SCI NOC	NOC updated
Qualiveen NOC	NOC updated
Satisfaction with Life Scale NOC	NOC updated
SF-36 Walk-Wheel Modification for SCI NOC	NOC updated
World Health Organization Quality of Life Assessment (WHO-QOL)	NOC updated
Generalized Anxiety Disorder NOC (GAD-7)	NOC updated
Hospital Anxiety and Depression Scale NOC (HADS)	NOC updated
Impact of Event Scale NOC (IES)	NOC updated
Moorong Self-Efficacy Scale NOC	NOC updated
Multidimensional Scale of Perceived Social Support NOC	NOC updated
Patient Health Questionnaire – 9 NOC	NOC updated
Perceived Manageability Scale NOC	NOC updated; classification revised to Exploratory

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Document	Comments
Positive Affect and Well-Being Scale for the Neuro-QoL NOC	NOC updated
Fatigue Severity Scale NOC	New for SCI

October 2016 Revisions

- Pain Extended Data Set v1.0 posted

June 2016 Revisions

- Endocrine and Metabolic Extended Data Set v1.0 posted

February 2016 Revisions

- Pediatric SCI CDE recommendations posted (See table for summary of pediatric updates):

Document	Updated for Pediatric SCI	New Document for SCI	Comment
Summary of Recommendations for Pediatric SCI		X	
Demographics	X		Pediatric-specific CDEs added
General Core	X		Pediatric specifications added
Alcohol and Tobacco Use	X		Pediatric specifications added
AUDIT	X		Pediatric classification added
Substance Use	X		Pediatric specifications added
Food Frequency Questionnaire	X		Pediatric instructions added

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Document	Updated for Pediatric SCI	New Document for SCI	Comment
Youth Adolescent Questionnaire (YAQ)		X	N/A
Child and Diet Evaluation Tool (CADET)		X	N/A
Calcium Counts Food Frequency Questionnaire		X	N/A
Birth Injury		X	N/A
Pre-Hospital Assessment	X		Pediatric specifications added
Acute Admission/Discharge	X		Pediatric CDEs added
Rehabilitation Admission/Discharge	X		Pediatric CDEs added
Clinical Assessment	X		Pediatric CDEs added
Spinal Cord Injury Pressure Ulcer Scale (SCIPUS)	X		Pediatric instructions added
Braden Q Scale		X	N/A
Swallowing Disturbance Questionnaire	X		Pediatric instructions added
Laboratory Tests	X		CDEs updated
Spinal Cord Imaging	X		Pediatric specifications added
Rehabilitation Therapies	X		Pediatric CDEs added
SCI Falls Diary		X	N/A

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Document	Updated for Pediatric SCI	New Document for SCI	Comment
Assistive/Mobility Devices and Orthoses		X	N/A
ISNCSCI	X		Pediatric specifications added
Modified Ashworth Scale	X		Pediatric classification added
Tardieu Scale	X		Pediatric classification added
Spinal Cord Assessment Tool for Spastic Reflexes	X		Pediatric classification added
NINDS Myotatic Reflex Scale	X		Pediatric classification added
Penn Spasm Frequency Scale	X		Pediatric classification added
Pendulum (Wartenberg) Test	X		Pediatric classification added
Peripheral Nerve Studies	X		Pediatric specifications added
Quantitative Sensory Testing	X		Pediatric specifications added
Electrical Perceptual Threshold	X		Pediatric specifications added
Sensory Evoked Potentials	X		Pediatric specifications added
Motor Evoked Potentials	X		Pediatric specifications added
Brain Motor Control Assessment	X		Pediatric specifications and reference added
Sympathetic Skin Responses	X		Pediatric specifications and reference added

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Document	Updated for Pediatric SCI	New Document for SCI	Comment
Berg Balance Scale	X		Pediatric classification and reference added
Quadriplegia Index of Function	X		Pediatric instructions added
SCI-Functional Ambulation Inventory (SCI-FAI)	X		Pediatric classification added
Sollerman Hand Function Test	X		Pediatric instructions added
SCI-Functional Index (SCI-FI)	X		Pediatric instructions and references added
Activities Based Balance Level Evaluation (ABLE) Scale	X		Pediatric instructions added
10 M Timed Walk	X		Pediatric classification added
2 Minute Walk	X		Pediatric classification added
6 Minute Walk Test	X		Pediatric classification added
Bayley Scales of Infant Development		X	N/A
Borg rating of Perceived Exertion Scale	X		Pediatric references and classification added
Bruininks-Oseretky Test of Motor Proficiency		X	N/A
Capabilities of Upper Extremity Questionnaire	X		Pediatric classification added
Canadian Occupational Performance Measure	X		Pediatric classification and references added
Capabilities of Upper Extremity Test	X		Pediatric classification added

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Document	Updated for Pediatric SCI	New Document for SCI	Comment
Five Times Sit to Stand Test	X		Pediatric classification and references added
Grasp and Release Test	X		Pediatric classification and references added
GRASSP	X		Pediatric classification added
Gross Motor Function Measure	X		Pediatric classification and references added
International SCI Upper Extremity Basic Data Set	N/A		Pediatric classification and references added
Jebsen-Taylor Hand Function Test	X		Pediatric classification added
Neuromuscular Recovery Scale	X		Pediatric classification and references added
Pediatric Neuromuscular Recovery Scale		X	N/A
NIH NeurQoL Pediatric Functional Health		X	N/A
Nine Hole Peg Test	X		Pediatric classification and references added
Pediatric Activity Measures		X	N/A
Peabody Developmental Motor Scales	X		Pediatric classification and references added
Pediatric Evaluation of Disability Inventory (PEDI)	X		Pediatric classification and references added
Pediatric PROMIS Measures		X	N/A
SC Independence Measure (SCIM)	X		Pediatric classification added

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Document	Updated for Pediatric SCI	New Document for SCI	Comment
SCIMeasure – Self Report for Youth		X	N/A
Segmental Assessment of Trunk Control		X	N/A
Stair Climb	X		Pediatric classification and references added
Stride Analysis and Gait Variability	X		Pediatric classification added
Tetraplegia Hand Activity Questionnaire	X		Pediatric classification added
Timed Up and Go	X		Pediatric classification and references added
Walking Index in SCI	X		Pediatric classification and references added
WeeFIM		X	N/A
Wheelchair Skills Test	X		Pediatric classification and references added
Wheelchair Circuit	X		Pediatric classification and references added
Children’s Activity Limitations Inventory (CALI)		X	N/A
Functional Disability Inventory		X	N/A
Adolescent and Pediatric Pain Tool		X	N/A
Multidimensional Pain Inventory – Pain Severity Subscale	X		Pediatric classification added
Faces Pain Scale		X	N/A

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Document	Updated for Pediatric SCI	New Document for SCI	Comment
Child Health Questionnaire Youth Version		X	N/A
Pediatric Measure of Participation (PMoP) CAT of SF		X	N/A
Child and Adolescent Scale of Participation (CASP)		X	N/A
SF-36		X	N/A
SWLS-C		X	N/A
Euro-QoL 5 Dimension Questionnaire		X	N/A
Generalized Anxiety Disorder – 7 (GAD7)	X		Pediatric classification added
Hospital Anxiety and Depression Scale (HADS)	X		Pediatric classification added
Impact of Event Scale	X		Pediatric instructions added
Children PTSD Symptom Scale (CPSS)		X	N/A
Moorong Self-Efficacy Scale (MSEST)	X		Pediatric instructions added
Multidimensional Scale of Perceived Social Support	X		Pediatric classification added
Patient Health Questionnaire (PHQ-9)	X		Pediatric classification added
Perceived Manageability Scale (PMnac)	X		Pediatric instructions added
Positive Affect and Well-Being Scale of the Neurology Quality of Life (Neuro-QoL) Measure	X		Pediatric instructions added

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Document	Updated for Pediatric SCI	New Document for SCI	Comment
Children's Depression Inventory		X	N/A
Beck Youth Inventories – 2 nd Edition		X	N/A
Revised Children's manifest Anxiety Scale (RCMAS) 2 nd Edition		X	N/A
Children Impact of Traumatic Event Scale (CITES-13)		X	N/A
AASM: International Classification of Sleep Disorders Criteria	X		Pediatric classification added
Adolescent Sleep Wake Scale (ASWS)		X	N/A
Infant Sleep Questionnaire		X	N/A
Tayside Children's Sleep Questionnaire		X	N/A
Epworth Sleepiness Scale (ESS) – Children's Version		X	N/A
Functional Outcomes of Sleep Questionnaire (FOSQ)	X		Pediatric instructions added
Adolescent Sleep Hygiene Scale		X	N/A
Berlin Questionnaire	X		Pediatric instructions added
Obstructed Sleep Apnea – 18 (OSA-18)		X	N/A
Children's Sleep Habits Questionnaire (CSHQ) – Preschool and School Age		X	N/A
Children's Sleep Habits Questionnaire (CSHQ) – Older Child/Adolescent		X	N/A

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Document	Updated for Pediatric SCI	New Document for SCI	Comment
Pediatric Sleep Questionnaire		X	N/A
Pittsburgh Sleep Quality Index	X		Pediatric classification added
Brief Infant Sleep Questionnaire (BISQ)		X	N/A

September 2015 Revisions

- SCI Endocrine and Metabolic Basic Data Set v2.0 posted
- Cardiovascular Function Basic Data Set v1.1 posted

April 2015 Revisions

- Revised the layout of the SCI Rehabilitation Therapies CRF.
- Inserted additional reference on the 6 Minute Walk Test file.
- Added the Pediatric SCI Working Group to the SCI Roster Report.

March 2015 Revisions

- Added the following article to the references page in SCI:

Fin Biering-Sørensen, Sherita Alai, Kim Anderson, Susan Charlifue, Yuying Chen, Michael DeVivo, Adam E. Flanders, Linda Jones, Naomi Kleitman, Aria Lans, Vanessa K. Noonan, Joanne Odenkirchen, John Steeves, Keith Tansey, Eva Widerström-Noga, Lyn B. Jakeman. Common Data Elements for Spinal Cord Injury Clinical Research: A National Institute for Neurological Disorders and Stroke Project. [Spinal Cord](#). 2015 Feb 10
- Modified Overview tab on SCI landing page.
- Revised Surgical and Procedural Interventions CRF in SCI to correct data entry mistakes found in the form.

February 2015 Revisions

No changes.

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January 2015 Revisions

- Posting of revised 508 compliant Start-Up and Highlight Summaries.
- Addition of new ISCoS Injury Spinal Intervention and Spinal Procedures Basic Data Set and CRF in SCI.
- Data correction changes to CRFs in SCI.
- Dr. Lawrence C. Vogel and Dr. MJ Mulcahey were added to the SCI roster as Co-Chairs of the Pediatric Working Group.

November 2014 Revisions

- Changes were made to the rosters: Changed Dr. David Tulsy's institution from the University of Michigan to the University of Delaware in SCI.
- Formatting changes were made to 5 CRFs in SCI.

September 2014 Revisions

- Corrections to various CRFs in SCI (minor changes).
- Updated CDEs for Magnetic Resonance Imaging in SCI.

August 2014 Revisions

- 508-compliant versions of various CRFs, NOCs, Guidelines, Startup and Highlights documents, and other downloadable files posted SCI.

Overview

There have been changes to the content and structure of the SCI CDEs since the previous release including:

Form Status Changes

New Forms:

- Imaging

Updated Forms:

- History of Injury
- Demographics

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- Surgical and Procedural Interventions
- Medical History
- Rehabilitation Therapies
- Start-Up Resource
- Highlight Resource

Removed Forms:

- None

Other Changes:

The domains and sub-domains for SCI have been revised based on recommendations from subject matter experts. They have been reorganized to align with users' needs as follows:

NIH Resources

- NIH Resources

Participant Characteristics

- Demographics

Participant History and Family History

- General Health History
- Epidemiology/ Environmental History

Disease/ Injury Related Events

- History of Disease/ Injury Event

Assessments and Examinations

- Hospital/ Care Management
- Physical Examinations
- Neurological Examination
- Vital Signs and Laboratory Tests
- Spinal Imaging/ Spinal Cord Imaging

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Treatment/ Intervention Data

- Drugs

Protocol Experience

Safety Data

Outcomes and End Points

- Neurological Outcomes
- Electrodiagnostics
- Functional Outcomes
- Pain
- Participation and Quality of Life
- Psychological Status
- Sleep

The International SCI Data Sets

- The International SCI Data Sets

Prospective Assessments for Suicidal Ideation and Behavior

June 2014 Revisions

Overview

There have been changes to the content and structure of the SCI CDEs since the previous release including:

The SCI Working Groups and the NINDS CDE Team have released the first version (version 1.0) of the SCI CDEs. SCI Working Groups were the following: (1) Demographic; (2) Care; (3) Electrodiagnostics; (4) Functional; (5) Imaging; (6) Neurological; (7) Pain; (8) Psychological; and (9) Participation/Quality of Life.

Form Status Changes

New Forms:

Care Subdomain

- Spinal Cord Care Injury CDE Structure

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- Medical History
- Prior and Concomitant Medications
- Alcohol and Tobacco Use
- Alcohol Use Disorders Identification Test: Self-Report Version (AUDIT)
- Substance Use
- Food Frequency Questionnaire (FFQ)
- Family History
- History of Injury
- Pre-Hospital Assessment Form
- Physical Exam
- Clinical Assessment
- Spinal Cord Injury Pressure Ulcer Scale (SCIPUS)
- Braden Scale
- Swallowing Disturbance Questionnaire (SwDQ)
- Vital Signs and Tests
- The American Academy of Sleep Medicine (AASM): International Classification of Sleep Disorders (ICSD) Criteria
- Berlin Questionnaire
- Epworth Sleepiness Scale (ESS)
- Functional Outcomes of Sleep Questionnaire (FOSQ)
- Pittsburgh Sleep Quality Index (PSQI)
- Laboratory Tests
- Surgical and Procedural Interventions
- Other Investigational Treatments
- Rehabilitation Admission/Discharge

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- Rehabilitation Therapies
- Acute Admission/Discharge
- Adverse Events

Demographics Subdomain

- Demographics

Electrodiagnostics Subdomain

- Algorithm for Using Spinal Cord Injury Electrodiagnostic CDEs
- Brain Motor Control Assessment
- Electrical Perceptual Threshold
- Motor Evoked Potential (MEP)
- Peripheral Nerve Studies
- Quantitative Sensory Testing (QST)
- Sensory Evoked Potentials
- Sympathetic Skin Response

Functional Subdomain

- Functional Instrument Recommendations
- 10 Meter Timed Walk
- 2 Minute Walk Test
- 6 Minute Walk Test
- Berg Balance Scale
- Borg Dyspnea Scale
- Canadian Occupational Performance Measure (COPM)
- Capabilities Upper Extremity Questionnaire
- Capabilities Upper Extremity Test (CUE-T)
- Five Times to Sit and Stand Test

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- Graded Redefined Assessment of Strength, Sensibility and Prehension (GRASSP)
- Grasp and Release Test
- International Spinal Cord Injury Upper Extremity Basic Data Set
- Jebsen-Taylor Hand Functioning Test
- Neuromuscular Recovery Scale
- Nine Hole Peg Test
- Quadriplegia Index Function
- Sollerman Test of Hand Function
- Spinal Cord Independence Measure
- Spinal Cord injury Functional Ambulation Inventory (SCI-FAI)
- Spinal Cord Injury Functional Index (SCI-FI)
- Stair Climb
- Stride Analysis and Gait Variability
- Tetraplegia Hand Activity Questionnaire
- The Activities Based Balance Evaluation (ABLE) Scale
- Timed Up and Go (TUG)
- Toronto Rehabilitation Institute Hand Function Test
- Walking Index for Spinal Cord Injury (WISC II)
- Wheelchair Circuit
- Wheelchair Skills Test

Imaging Subdomain

- Spinal Cord Injury CDE Imaging Guidelines
- Magnetic Resonance Imaging
- Diffusion Tensor Imaging
- Spinal Cord Imaging Modules-Diffusion Tensor Imaging

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- Imaging Protocol Table Sequencing 1.5T
- Imaging Protocol Table Sequencing for 3T

Neurological Subdomain

- Spinal Cord Injury Neurological Instrument Recommendations
- Modified Ashworth Scale for Grading Spasticity
- NINDS Myotatic Reflex Scale
- Pendulum (Wartenberg) Test
- Penn Spasm Frequency Scale
- Spinal Cord Assessment Tool for Spastic Reflexes (SCATS)
- Tardieu Scale

Pain Subdomain

- Pain Instrument Recommendations
- International SCI Pain Basic Data Subset
- Doleur Neuropathique 4 (DN4)
- Multidimensional Pain Inventory (MPI) Pain Severity Subscale
- Neuropathic Pain Questionnaire (NPQ)
- Neuropathic Pain Symptom Inventory (NPSI)
- Pain Quality Assessment Scale (PQAS)
- painDETECT

Participation/Quality of Life

- Participation/Quality of Life Instrument Recommendations
- Craig Handicap and Assessment Reporting Technique (CHART-SF)
- EuroQoL-5 Dimension Questionnaire
- Life Satisfaction Questionnaire (LISAT-9)
- Quality of Life Index (QLI) - SCI Version

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- Qualiveen
- Satisfaction with Life Scale
- Short Form Health Survey-36 (SF-36) Walk Wheel Modification for Spinal Cord Injury
- Spinal Cord Injury Multidimensional-Quality of Life (SCI-QOL)
- World Health Organization Quality of Life Assessment (WHOQOL-BREF)

Psychological Subdomain

- Psychological Instrument Recommendations
- Generalized Anxiety Disorder (GAD-7)
- Hospital Anxiety and Depression Scale (HADS)
- Impact of Event Scale (IES)
- Moorong Self-Efficacy Scale (MSES)
- Multidimensional Scale of Perceived Social Support
- Patient Health Questionnaire - 9 (PHQ-9)
- Perceived Manageability Scale (PMnac)
- Positive Affect and Well-Being Scale of the Neurology Quality of Life (Neuro-QOL) Measure

Updated Forms:

- International SCI Pain Basic Data Set

Removed Forms:

- None

Additional specific changes to the CRF Modules are detailed in the table included below.

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Table 1 June 2014 Revisions

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Spinal Cord Care Injury CDE Structure	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials
Medical History	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Medical History
Prior and Concomitant Medications	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Prior and Concomitant Medications
Alcohol and Tobacco Use	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Alcohol and Tobacco Use
Alcohol Use Disorders Identification Test: Self-Report Version (AUDIT)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Substance Use	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Substance Use

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Food Frequency Questionnaire (FFQ)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Family History	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Family History
History of Injury	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to History of Injury
Pre-Hospital Assessment Form	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Pre-Hospital Assessment Form
Physical Exam	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Physical Exam
Clinical Assessment	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Clinical Assessment

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Spinal Cord Injury Pressure Ulcer Scale (SCIPUS)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Braden Scale	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Swallowing Disturbance Questionnaire (SwDQ)	2.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Vital Signs and Tests	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Vital Signs and Tests
The American Academy of Sleep Medicine (AASM): International Classification of Sleep Disorders (ICSD) Criteria	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Berlin Questionnaire	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Epworth Sleepiness Scale (ESS)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials

Spinal Cord Injury CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Functional Outcomes of Sleep Questionnaire (FOSQ)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Pittsburgh Sleep Quality Index (PSQI)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Laboratory Tests	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Laboratory Tests
Surgical and Procedural Interventions	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Surgical and Procedural Interventions
Other Investigational Treatments	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Other Investigational Treatments
Rehabilitation Admission/Discharge	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Rehabilitation Admission/Discharge
Rehabilitation Therapies	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Rehabilitation Therapies

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Acute Admission/Discharge	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Acute Admission/Discharge
Adverse Events	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Adverse Events
Demographics	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Demographics
Algorithm for Using Spinal Cord Injury Electrodiagnostic CDEs	1.0	N/A	Major	New Form	
Brain Motor Control Assessment	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Brain Motor Control Assessment
Electrical Perceptual Threshold	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Electrical Perceptual Threshold
Motor Evoked Potential (MEP)	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Motor Evoked Potential

Spinal Cord Injury CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Peripheral Nerve Studies	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Peripheral Nerve Studies
Quantitative Sensory Testing (QST)	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Quantitative Sensory Testing
Sensory Evoked Potentials	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Sensory Evoked Potentials
Sympathetic Skin Response	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Sympathetic Skin Response
Functional Instrument Recommendations	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials
10 Meter Timed Walk	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
2 Minute Walk Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
6 Minute Walk Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials

Spinal Cord Injury CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Berg Balance Scale	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Borg Dyspnea Scale	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Canadian Occupational Performance Measure (COPM)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Capabilities Upper Extremity Questionnaire	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Capabilities Upper Extremity Test (CUE-T)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Five Times to Sit and Stand Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Graded Redefined Assessment of Strength, Sensibility and Prehension (GRASSP)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Grasp and Release Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials

Spinal Cord Injury CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
International Spinal Cord Injury Upper Extremity Basic Data Set	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to International Spinal Cord Injury Upper Extremity Basic Data Set
Jebsen-Taylor Hand Functioning Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Neuromuscular Recovery Scale	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Nine Hole Peg Test	2.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Quadriplegia Index Function	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Sollerman Test of Hand Function	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Spinal Cord Independence Measure	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Spinal Cord injury Functional Ambulation Inventory (SCI-FAI)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials

Spinal Cord Injury CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Spinal Cord Injury Functional Index (SCI-FI)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Stair Climb	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Stride Analysis and Gait Variability	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Tetraplegia Hand Activity Questionnaire	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
The Activities Based Balance Evaluation (ABLE) Scale	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Timed Up and Go (TUG)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Toronto Rehabilitation Institute Hand Function Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Walking Index for Spinal Cord Injury (WISC II)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Wheelchair Circuit	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Wheelchair Skills Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Spinal Cord Injury CDE Imaging Guidelines	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials
Magnetic Resonance Imaging	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Magnetic Resonance Imaging
Diffusion Tensor Imaging	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials to capture CDEs related to Diffusion Tensor Imaging
Spinal Cord Imaging Modules-Diffusion Tensor Imaging	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials
Imaging Protocol Table Sequencing 1.5T	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials
Imaging Protocol Table Sequencing for 3T	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials
Spinal Cord Injury Neurological Instrument Recommendations	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials
Modified Ashworth Scale for Grading Spasticity	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials

Spinal Cord Injury CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
NINDS Myotatic Reflex Scale	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Pendulum (Wartenberg) Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Penn Spasm Frequency Scale	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Spinal Cord Assessment Tool for Spastic Reflexes (SCATS)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Tardieu Scale	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Pain Instrument Recommendations	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials
Doleur Neuropathique 4 (DN4)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Multidimensional Pain Inventory (MPI) Pain Severity Subscale	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Neuropathic Pain Questionnaire (NPQ)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Neuropathic Pain Symptom Inventory (NPSI)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Pain Quality Assessment Scale (PQAS)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
painDETECT	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Participation/Quality of Life Instrument Recommendations	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials
Craig Handicap and Assessment Reporting Technique (CHART-SF)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
EuroQoL-5 Dimension Questionnaire	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Life Satisfaction Questionnaire (LISAT-9)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Quality of Life Index (QLI) - SCI Version	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Qualiveen	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials

Spinal Cord Injury CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Satisfaction with Life Scale	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Short Form Health Survey-36 (SF-36) Walk Wheel Modification for Spinal Cord Injury	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Spinal Cord Injury Multidimensional-Quality of Life (SCI-QOL)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
World Health Organization Quality of Life Assessment (WHOQOL-BREF)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Psychological Instrument Recommendations	1.0	N/A	Major	New Form	A New Form was created and added to the SCI CDE materials
Generalized Anxiety Disorder (GAD-7)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Hospital Anxiety and Depression Scale (HADS)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Impact of Event Scale (IES)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Moorong Self-Efficacy Scale (MSES)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Multidimensional Scale of Perceived Social Support	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Patient Health Questionnaire - 9 (PHQ-9)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Perceived Manageability Scale (PMnac)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
Positive Affect and Well-Being Scale of the Neurology Quality of Life (Neuro-QOL) Measure	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the SCI CDE materials
International SCI Pain Basic Data Set	1.0	N/A	Major	Updated Form	A new version of the International SCI Pain Basic Data Set was created and added to the SCI CDE materials

January 2013 Revisions

Overview

The SCI CDEs continue to be 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)]

Form Status Changes

New Forms:

- International SCI Urinary Tract Infection Basic Data Set

Updated Forms:

- None

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Removed Forms:

- None

Additional specific changes to the CRF Modules are detailed in the table included below.

2 Spinal Cord Injury Revision History Table

CRF Module/ Guideline	Current Version*	Previous Version	Change Classification	Change Type	Description of Change
International SCI Urinary Tract Infection Basic Data Set	1.0	N/A	Major	New Form	A copy of this data set, which was originally, developed by the International SCI Standards and Data Sets committees, and its associated CDEs were added to the Web site.

August 2012 Revisions

Overview

There have been changes to the content and structure of the SCI CDEs since the previous release including:

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

The SCI 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; and

The permissible values and references of some elements were revised.

Form Status Changes

New Forms:

Spinal Cord Injury CDE Revision History Document

- International SCI Musculoskeletal Basic Data Set
- International Non-Traumatic Spinal Cord Injury Basic and Extended Data Sets

Updated Forms:

- None

Removed Forms:

- None

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

3 Spinal Cord Injury Revision History Table

CRF Module/ Guideline	Current Version*	Previous Version	Change Classification	Change Type	Description of Change
All	1.0	1.0	Minor	Modified CDEs	Nearly all CDE names and definitions were updated to achieve greater consistency with other NINDS CDEs.
Various	1.0	1.0	Major	Modified CDEs	Many CDE codes, definitions for codes, data types, instructions, and references were modified
All	1.0	1.0	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.

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CRF Module/ Guideline	Current Version*	Previous Version	Change Classification	Change Type	Description of Change
All	1.0	1.0	Minor	Modified CDEs	CDEs that allowed free text to specify an answer of "Other" were merged into the preceding element.
Various	1.0	1.0	Minor	Deleted CDEs	The following types of CDEs were deleted: CDEs redundant with other CDEs; CDEs specifying unit; and CDEs specifying an "other, specify" response
Various	1.0	1.0	Minor	Modified CDEs	Population information was added to be consistent with other NINDS CDEs
Various	1.0	1.0	Minor	Modified CDEs	Similar indicator questions were consolidated from multiple CDEs into one CDE with multiple permissible values (i.e., one permissible value representing each original indicator question)
Various	1.0	1.0	Minor	New CDEs	Laterality CDEs were created to reduce replication of the same CDE for different sides of the body
International SCI Musculoskeletal Basic Data Set	1.0	N/A	Major	New Form	A copy of this data set, which was originally developed by the International SCI Standards and Data Sets committees, and its associated CDEs were added to the Web site.

Spinal Cord Injury CDE Revision History Document

CRF Module/ Guideline	Current Version*	Previous Version	Change Classification	Change Type	Description of Change
International Non-Traumatic Spinal Cord Injury Basic and Extended Data Sets	1.0	N/A	Major	New Form	A copy of this data set, which was originally developed by the International SCI Standards and Data Sets committees, and its associated CDEs were added to the Web site.