Start-up Resource – NINDS Spinal Cord Injury (SCI) CDE Recommendations

The National Institute of Neurological Disorders and Stroke (NINDS) and other Federal agencies and international organizations have the common mission of developing data standards for clinical research. Through the efforts of subject-specific working groups, topic-driven data elements have been created. The first set of Common Data Elements (CDEs) for Spinal Cord Injury was developed in 2014. The Core and Supplemental – Highly Recommended data elements to be used by an investigator when beginning a research study in this disease/disorder are listed in this resource document. All other recommendations are listed on the website and should be considered based on study type.

Each CDE or instrument could be classified according to the definitions below:

**General Core**: A data element that is required for all NINDS funded studies.

**Disease Core**: A data element that collects essential information applicable to any disease-specific study, including all therapeutic areas. The NINDS and its appointed working groups assign the disease “Core” classification based on the current clinical research best practices. In each case, the disease Core CDEs are a small subset of the available CDEs, where it is anticipated that investigators will need to collect the disease Core CDEs on any type of study. These are required for all disease-specific studies.

**Disease Supplemental - Highly Recommended**: A data element which is essential based on certain conditions or study types in clinical research studies. In most cases, these have been used and validated in the disease area. These data elements are strongly recommended for the specified disease condition, study type or design.

**Disease Supplemental**: A data element which is commonly collected in clinical research studies. Use depends upon the study design, protocol or type of research involved. These are recommended, but not required, for studies.

**Disease Exploratory**: A data element that requires further validation, but may fill current gaps in the CDEs and/or substitute for an existing CDE once validation is complete. Such data elements show great promise, but require further validation before they are ready for prime-time use in clinical research studies. They are reasonable to use with the understanding that it has limited validation in the target group.
Summary of Core/Supplemental - Highly Recommended Recommendations: Spinal Cord Injury CDEs

National Institute of Health (NIH) Resources:
The NINDS also strongly encourages researchers to use these NIH developed materials for NINDS-sponsored research, when appropriate. Utilization of these resources will enable greater consistency for NINDS-sponsored research studies. These tools are free of charge.

- NIH Toolbox
- Quality of Life in Neurological Disorders (Neuro-QOL)
- Patient-Reported Outcomes Measurement Information System (PROMIS)

Core CDEs for ALL NINDS Studies*:

<table>
<thead>
<tr>
<th>CDE Domain</th>
<th>CDE Name</th>
<th>CDE ID</th>
<th>Classification</th>
<th>Study Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td>Birth date</td>
<td>C00007</td>
<td>CORE</td>
<td>All studies</td>
</tr>
<tr>
<td>Demographics</td>
<td>Ethnicity USA category</td>
<td>C00020</td>
<td>CORE</td>
<td>All studies</td>
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<tr>
<td>Demographics</td>
<td>Race USA category</td>
<td>C00030</td>
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<tr>
<td>Demographics</td>
<td>Gender Type</td>
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<td>CORE</td>
<td>All studies</td>
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<td>Medical history condition text</td>
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<td>All studies</td>
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<td>General Health History</td>
<td>Medical history condition SNOMED CT code</td>
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</table>

Core CDEs for SCI Studies:

<table>
<thead>
<tr>
<th>CDE Domain; Subdomain</th>
<th>CDE Name</th>
<th>CDE ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease/ Injury Related Events; History of Disease/Injury Event</td>
<td>Visit date</td>
<td>C17409</td>
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<tr>
<td>Disease/ Injury Related Events; History of Disease/Injury Event</td>
<td>Injury date time</td>
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<tr>
<td>Disease/ Injury Related Events; History of Disease/Injury Event</td>
<td>Spinal cord injury etiology type</td>
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<tr>
<td>Participant Characteristics; Demographics</td>
<td>Less three years age value</td>
<td>C18386*</td>
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* Note: Education year count C00015 is no longer a general Core CDE

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### Supplemental – Highly Recommended CDEs for SCI Studies:

<table>
<thead>
<tr>
<th>CDE Domain</th>
<th>CDE Name</th>
<th>CDE ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant Characteristics/Participant History and Family History</td>
<td>Education year count</td>
<td>C00015</td>
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<tr>
<td>Participant Characteristics/Participant History and Family History</td>
<td>Family income range</td>
<td>C00205</td>
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<tr>
<td>Participant Characteristics/Participant History and Family History</td>
<td>Education level primary caregiver USA type</td>
<td>C00013*</td>
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<tr>
<td>Participant Characteristics/Participant History and Family History</td>
<td>Education level USA type</td>
<td>C00012*</td>
</tr>
<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>Multiple birth indicator</td>
<td>C15985*</td>
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<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>Twin sibling vital status</td>
<td>C21621*</td>
</tr>
<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>Pregnancy or delivery risk factor type</td>
<td>C11066*</td>
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<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>Respiratory intervention neonatal problem type</td>
<td>C12625*</td>
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<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>Deliver condition hypotonia grade</td>
<td>C12631*</td>
</tr>
<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>Gestational age range value</td>
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<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>Delivery mode type</td>
<td>C11078*</td>
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<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>Neonate delivery route type</td>
<td>C11079*</td>
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## Summary of Core/Supplemental - Highly Recommended Recommendations: Spinal Cord Injury CDEs

<table>
<thead>
<tr>
<th>CDE Domain</th>
<th>CDE Name</th>
<th>CDE ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>Caesarean delivery timing type</td>
<td>C17983*</td>
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<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>Delivery modality type</td>
<td>C11080*</td>
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<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>Delivery extraction type</td>
<td>C11083*</td>
</tr>
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<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>APGAR one minute score</td>
<td>C12604*</td>
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<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>APGAR five minute score</td>
<td>C00724*</td>
</tr>
<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>APGAR ten minute score</td>
<td>C00723*</td>
</tr>
<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>Neonatal intensive unit stay indicator</td>
<td>C12628*</td>
</tr>
<tr>
<td>Disease/Injury Related Events; History of Disease/Injury Related Events</td>
<td>Neonatal intensive care unit stay duration</td>
<td>C12629*</td>
</tr>
</tbody>
</table>

### Core Instruments for all SCI studies:

<table>
<thead>
<tr>
<th>CDE Domain</th>
<th>Category</th>
<th>Instruments/Data Sets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurological</td>
<td>CNS Sensorimotor Impairment (or Preservation)</td>
<td>[International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI)]</td>
</tr>
<tr>
<td>N/A</td>
<td>Columbia Suicidal Ideation Assessment</td>
<td>[Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials]</td>
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</table>
**Summary of Core/Supplemental - Highly Recommended Recommendations: Spinal Cord Injury CDEs**

**NINDS Highly-recommended Instrument Recommendations for SCI Studies:**

Supplemental – Highly Recommended Instruments and Data Sets by Domain

<table>
<thead>
<tr>
<th>CDE Domain</th>
<th>Category</th>
<th>Instruments/Data Sets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional</td>
<td>Gait</td>
<td>10 Meter Walk Test</td>
</tr>
<tr>
<td>Functional</td>
<td>Gait</td>
<td>6 Minute Walk Test</td>
</tr>
<tr>
<td>Functional</td>
<td>Balance</td>
<td>Berg Balance Scale**</td>
</tr>
<tr>
<td>Functional</td>
<td>Upper Extremity</td>
<td>International SCI Upper Extremity Basic Data Set</td>
</tr>
<tr>
<td>Functional</td>
<td>Overall Function</td>
<td>Pediatric Evaluation of Disability Inventory (PEDI)*</td>
</tr>
<tr>
<td>Functional</td>
<td>Overall Function</td>
<td>Spinal Cord Independence Measure</td>
</tr>
<tr>
<td>Pain</td>
<td>Multiple</td>
<td>International SCI Pain Basic Data Set Version 2.0</td>
</tr>
<tr>
<td>Psychological</td>
<td>Depression</td>
<td>Patient Health Questionnaire 9 (PHQ-9)</td>
</tr>
<tr>
<td>Psychological</td>
<td>Anxiety and Depression</td>
<td>Hospital Anxiety and Depression Scale (HADS)</td>
</tr>
</tbody>
</table>

*Pediatric SCI recommendation
**Not recommended for youth < 18

For the complete list of NINDS CDE recommendations for SCI, please see the [NINDS CDE website](https://www.ninds.nih.gov/).