

### Start-up Resource – NINDS Traumatic Brain Injury CDE Recommendations

The National Institute of Neurological Disorders and Stroke (NINDS) and several Co-sponsoring Federal agencies 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 CDEs was developed in 2010 and was well-suited for hospital-based studies of acute TBI in adults. To broaden the utility of the TBI CDEs, experts were asked to update the recommendations to make them relevant to all ages, injury severity, and phases of recovery. The second version of the TBI CDEs (v.2) was developed in 2012. The Core 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 Recommendations: Traumatic Brain Injury CDEs

<p><b>National Institute of Health (NIH) Resources:</b>  <i>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.</i></p>	<ul style="list-style-type: none"> <li>• NIH Toolbox             <ul style="list-style-type: none"> <li>• Quality of Life in Neurological Disorders (Neuro-QOL)</li> </ul> </li> <li>• Patient-Reported Outcomes Measurement Information System (PROMIS)</li> </ul>
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### Core CDEs for all NINDS Studies<sup>1</sup>:

CDE Domain	CDE Name	CDE ID	Classification	Study Type
Demographics	Birth date	C00007	CORE	All studies
Demographics	Ethnicity USA category	C00020	CORE	All studies
Demographics	Race USA category	C00030	CORE	All studies
Demographics	Gender Type	C00035	CORE	All studies
General Health History	Medical history condition text	C00322	CORE	All studies
General Health History	Medical history condition SNOMED CT code	C00313	CORE	All studies

### Core CDEs for Traumatic Brain Injury Studies:

Domain; Sub-domain	CDE Name	CDE ID
Participation/Subject Characteristics; Social Status	Education school participation status	C00202
Participation/Subject Characteristics; Social Status	Employment status	C00204
Outcomes and Endpoints; Global Outcome	Glasgow Outcome Scale Extended (GOS-E) – score	C07194
Disease/Injury Related Events; History of Disease/Injury Event	Injury date time	C05400

<sup>1</sup> Note: Education year count C00015 is no longer a general Core CDE



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Domain; Sub-domain	CDE Name	CDE ID
Disease/Injury Related Events; History of Disease/Injury Event	TBI type	C05420
Disease/Injury Related Events; History of Disease/Injury Event	Injury ICD external cause code	C05421
Disease/Injury Related Events; History of Disease/Injury Event	ICD revision number	C18609
Disease/Injury Related Events ; Classification	Subarachnoid hemorrhage indicator	C02469
Physical/Neurological Examination	Loss of consciousness duration range	C01053
Assessments and Examinations; Physical/Neurological Examination	Post traumatic amnesia duration range	C01055
Assessments and Examinations; Imaging Diagnostics	Imaging brain assessment result	C02500

### General Core for all Studies:

Investigators should review the FDA's ["Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials"](#) for the most up-to-date information about suicidal ideation and behavior. One scale that FDA suggests is the Columbia Suicide Severity Rating Scale (C-SSRS) (available at [Columbia Suicide Severity Rating Scale Website](#)).

### Core Instrument for Traumatic Brain Injury Studies:

[Glasgow Outcome Scale – Extended \(GOSE\)](#)

For the complete list of NINDS CDE recommendations for TBI, please see the [NINDS CDE website](#).