Summary of Core and Supplemental-Highly Recommended (for Biomechanical Devices in TBI) Recommendations: Traumatic Brain Injury CDEs

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. In 2017, the Biomechanical Devices in Traumatic Brain Injury (TBI) CDE Working Group was developed with addition of Supplemental-Highly Recommended data elements.

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.

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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[1]:

Domain/Sub-Domain	CDE Name	CDE ID	Study Type
Participant Characteristics; Demographics	Birth date	C00007	All studies
Participant Characteristics; Demographics	Ethnicity USA category	C00020	All studies
Participant Characteristics; Demographics	Race USA category	C00030	All studies
Participant Characteristics; Demographics	Birth sex assigned type	C58676	All studies
Participant Characteristics; Demographics	Gender identity type	C58677	All studies
Participant History and Family History; General Health History	Medical history condition text	C00322	All studies
Participant History and Family History; General Health History	Medical history condition SNOMED CT code	C00313	All studies

[1] Note: Education year count C00015 is no longer a General Core CDE

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Core CDEs for Traumatic Brain Injury Studies:

Domain; Sub-domain	CDE Name	CDE ID
Participation/Subject Characteristics; Demographics	Race expanded category	C00031
Participation/Subject Characteristics; Demographics	Sex participant or subject genotype other text	C18751
Participation/Subject Characteristics; Demographics	Sex participant or subject genotype type	C17396
Participation/Subject Characteristics; Social Status	Education school participation status	C00202
Participation/Subject Characteristics; Social Status	Employment expanded status	C18658
Participation/Subject Characteristics; Social Status	Employment expanded other text	C18676
Participation/Subject Characteristics; Social Status	Education year count	C00015
Participation/Subject Characteristics; Social Status	Education primary caregiver year count	C18614
Disease/Injury Related Events; History of Disease/Injury Event	Injury date time	C05400
Disease/Injury Related Events; History of Disease/Injury Event	Injury elapsed time	C17404
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

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Domain; Sub-domain	CDE Name	CDE ID
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)

Supplemental-Highly Recommended for Biomechanical Devices in TBI (List under Domain of Disease/Injury Related Events):

CRF Module	CDE Name	CDE ID
Head Kinematics Estimates Form	Subject ID	C19247
Head Kinematics Estimates Form	Head impact count	C56877
Head Kinematics Estimates Form	Biomechanical device sensor other text	C58451
Head Kinematics Estimates Form	Biomechanical device sensor type	C56859

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CRF Module	CDE Name	CDE ID
Head Kinematics Estimates Form	Biomechanical device sensor manufacturer name	C56860
Head Kinematics Estimates Form	Biomechanical device sensor model name	C56862
Head Kinematics Estimates Form	Biomechanical device hardware version number	C56867
Head Kinematics Estimates Form	Biomechanical device sensor firmware version number code	C56868
Head Kinematics Estimates Form	Software version number	C57000
Head Kinematics Estimates Form	Biomechanical head device type	C56869
Head Kinematics Estimates Form	Anatomical sensing device location	C57001
Head Kinematics Estimates Form	Pre-trigger impact duration	C57002
Head Kinematics Estimates Form	Post-trigger impact duration	C57003
Head Kinematics Estimates Form	Total record length impact duration	C57004
Head Kinematics Estimates Form	Data storage trigger threshold value	C57005
Head Kinematics Estimates Form	Linear acceleration unit of measure	C56903
Head Kinematics Estimates Form	Head accelerometer range	C56884
Head Kinematics Estimates Form	Head accelerometer sample rate value	C56885

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CRF Module	CDE Name	CDE ID
Head Kinematics Estimates Form	Sensor direct measure angular velocity measurement type	C57014
Head Kinematics Estimates Form	Gyroscope range	C56889
Head Kinematics Estimates Form	Gyroscope sample rate value	C56890
Head Kinematics Estimates Form	Data transform sensor coordinate system definition text	C56897
Head Kinematics Estimates Form	Society of Automotive Engineers impact test data filter indicator	C56898
Head Kinematics Estimates Form	Data filter specification text	C56899
Head Kinematics Estimates Form	Data filter type	C56900
Head Kinematics Estimates Form	Peak linear acceleration unit of measure	C57021
Head Kinematics Estimates Form	Head impact peak linear acceleration x value	C56908
Head Kinematics Estimates Form	Head impact peak linear acceleration y value	C56909
Head Kinematics Estimates Form	Head impact peak linear acceleration z value	C56910
Video Device Confirmation Form	Age value	C00008
Video Device Confirmation Form	Data collected start date and time	C56999

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CRF Module	CDE Name	CDE ID
Video Device Confirmation Form	Data collected date and time	C06005
Video Device Confirmation Form	Date time clock type	C22780
Video Device Confirmation Form	Activity description	C19144
Video Device Confirmation Form	Camera manufacturer name	C56788
Video Device Confirmation Form	Camera model type	C56789
Video Device Confirmation Form	Camera resolution type	C56790
Video Device Confirmation Form	Camera sample rate	C56791
Video Device Confirmation Form	Camera position type	C56792
Video Device Confirmation Form	Timestamp sensor video synchronization resolution error duration	C57028
Video Device Confirmation Form	Timestamp creation method type	C56793
Video Device Confirmation Form	Video device time synchronization method type	C56794
Video Device Confirmation Form	Video device verification method type	C56795
Video Device Confirmation Form	Video device analysis link method type	C56796
Video Device Confirmation Form	Video device analysis link method type other text	C56950

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CRF Module	CDE Name	CDE ID
Video Device Confirmation Form	Video device maximum allowable delta t value	C56797
Video Device Confirmation Form	Video device true positive impact count	C56798
Video Device Confirmation Form	Video device false positive count	C56799
Blast Exposure Form	Blast sensor charge describe text	C56806
Blast Exposure Form	Test description text	C56807
Blast Exposure Form	Test setup diagrams text	C56939
Blast Exposure Form	Blast sensor line of sight gauge target distance measurement	C56824
Blast Exposure Form	Blast sensor personnel gauge location	C56842
Blast Exposure Form	Blast sensor pressure time history text	C56843

For the complete list of NINDS CDE recommendations for TBI, please see the NINDS CDE website.