

FITBIR and NINDS Core CDEs for TBI Research

| Core CDEs recommended by NINDS for all studies ¹ | | | | |
|---|--|---|----------|---------------------|
| Domain/Sub-Domain | Title | Definition | NINDS ID | Population |
| Demographics | Birth date² | Date (and time, if applicable and known) the participant/subject was born. | C00007 | Adult and Pediatric |
| Demographics | Ethnicity USA category | Category of ethnicity the participant/subject most closely identifies with. | C00020 | Adult and Pediatric |
| Demographics | Gender Type | Self-reported gender of the participant/subject. Gender is the socially constructed identity of sex. Gender is equated with phenotypic sex. Gender may differ from the sex of an individual determined genetically. | C00035 | Adult and Pediatric |
| Demographics | Race USA category | The patient's self-declared racial origination, independent of ethnic origination, using OMB approved categories. | C00030 | Adult and Pediatric |
| General Health History | Medical history condition SNOMED CT code | Systematized Nomenclature Of Medicine Clinical Terms (SNOMED CT) code for medical condition/disease reported by the participant/subject. | C00313 | Adult and Pediatric |
| General Health History | Medical history condition text | Verbatim text for the medical condition/disease reported by the participant/subject or documented in the medical record as part of medical history. | C00322 | Adult and Pediatric |

¹ Updated on 05/17/2016

² FITBIR does not require to submit against "Birth Date" CDE.

Core CDEs recommended by [NINDS](#) and [FITBIR](#) for Traumatic Brain Injury studies

| Domain/Sub-Domain | Title | Definition | NINDS ID | Population |
|--|--|---|-----------------|---------------------|
| Participation/Subject Characteristics; Social Status | Education school participation status | Status of participant/subjects current attendance at school. | C00202 | Adult and Pediatric |
| Participation/Subject Characteristics; Social Status | Employment expanded status³ | Status of participant/subjects current employment. | C18658 | Adult and Pediatric |
| Participation/Subject Characteristics; Social Status | Employment expanded other text | The free-text field related to Employment expanded status specifying other text. Status of participant/subjects current employment. | C18676 | Adult and Pediatric |
| Disease/Injury Related Events; History of Disease/Injury Event | ICD revision number | Number of the International Classification of Diseases (ICD) used to obtain the code. | C18609 | Adult and Pediatric |
| Disease/Injury Related Events; History of Disease/Injury Event | Injury elapsed time⁴ | The elapsed time (in minutes) from the time of injury. | C17404 | Adult and Pediatric |
| Disease/Injury Related Events; History of Disease/Injury Event | Injury ICD external cause code | Code to classify the external cause of the injury. | C05421 | Adult and Pediatric |
| Assessments and Examinations; Imaging Diagnostics | Imaging brain assessment result | Result of the global assessment of brain imaging. | C02500 | Adult and Pediatric |

³ FITBIR uses the updated “Employment expanded status” CDE (C18658) instead of “[Employment status](#)” CDE (C00204) recommended by NINDS, because it provides more consistent way to capture employment information.

⁴ FITBIR uses “Injury elapsed time” CDE (C17404) instead of “[Injury date time](#)” CDE (C05400) recommended by NINDS, because many IRBs do not allow submitting injury date/time data. This does not preclude grantees from submitting “Injury date time”, if their IRB allows.

Core CDEs recommended by [NINDS](#) and [FITBIR](#) for **Traumatic Brain Injury studies** *continued*

| Domain/Sub-Domain | Title | Definition | NINDS ID | Population |
|---|--|--|-----------------|---------------------|
| Physical/Neurological Examination | Loss of consciousness duration range | The range of duration of loss of consciousness the participant/subject experienced. | C01053 | Adult and Pediatric |
| Assessments and Examinations; Physical/Neurological Examination | Post traumatic amnesia duration range | The range of duration of post-traumatic amnesia the participant/subject experienced. | C01055 | Adult and Pediatric |
| Disease/Injury Related Events ; Classification | Subarachnoid hemorrhage indicator | Indicator of macroscopic blood located between the brain surface and the arachnoid membrane. On CT and MR, the blood in this location will follow the contour of the sulci and cisterns. Acute SAH is hyperdense on CT and hyperintense on FLAIR MR imaging. | C02469 | Adult and Pediatric |
| Disease/Injury Related Events; History of Disease/Injury Event | TBI type | Broad classification of the type of traumatic brain injury experienced by participant/subject. | C05420 | Adult and Pediatric |
| Outcomes and Endpoints; Global Outcome | Glasgow Outcome Scale Extended (GOS-E) - Score | Glasgow Outcome Scale Extended (1-8). | C07194 | Adult |

Additional Core CDEs recommended by FITBIR for Traumatic Brain Injury studies

| Domain/Sub-Domain | Title | Definition | NINDS ID | Population |
|--|---|---|-----------------|---------------------|
| Demographics | Sex participant or subject genotype type | The difference between male and female, based upon the interactions between genes and between the genotype and the environment. Genotype is identified based on the individual's reproductive organs and functions assigned by chromosomal complement. | C17396 | Adult and Pediatric |
| Demographics | Sex participant or subject genotype other text | The free-text field related to Sex participant or subject genotype type specifying other text. The difference between male and female, based upon the interactions between genes and between the genotype and the environment. Genotype is identified based on the individual's reproductive organs and functions assigned by chromosomal complement. | C18751 | Adult and Pediatric |
| Demographics | Race category | Category of race(s) or region(s) the participant/subject most closely identifies with. | C00031 | Adult and Pediatric |
| Participation/Subject Characteristics; Social Status | Education year count | Number of years of education completed (age 5 and beyond). | C00015 | Adult and Pediatric |
| Participation/Subject Characteristics; Social Status | Education primary caregiver year count | Number of years of education of the primary caregiver (age 5 and beyond). | C18614 | Adult and Pediatric |
| Outcomes and Endpoints; Global Outcome | Glasgow Coma Scale (GCS) - Eye response scale | Glasgow Coma Scale (GCS) - Best eye response (E). The GCS is a standardized instrument for assessing the level of consciousness. It evaluates three aspects of responsiveness: eye opening, motor response, verbal response. | C01000 | Adult |
| Outcomes and Endpoints; Global Outcome | Glasgow Coma Scale (GCS) - Motor response scale | Glasgow Coma Scale (GCS) - Best motor response (M). The GCS is a standardized instrument for assessing the level of consciousness. It evaluates three aspects of responsiveness: eye opening, motor response, verbal response. | C01001 | Adult |

Additional Core CDEs recommended by FITBIR for Traumatic Brain Injury studies *continued*

| Domain/Sub-Domain | Title | Definition | NINDS ID | Population |
|--|---|---|-----------------|-------------------|
| Outcomes and Endpoints; Global Outcome | Glasgow Coma Scale (GCS) - Verbal response scale | Score that describes the participant's verbal response according to the Glasgow Coma Scale (GCS). | C01002 | Adult |
| Outcomes and Endpoints; Global Outcome | Glasgow Coma Scale (GCS) - Total score | Glasgow Coma Scale (GCS) - Total Score. The GCS is a standardized instrument for assessing the level of consciousness. It evaluates three aspects of responsiveness: eye opening, motor response, verbal response. The total score is the sum of the scores for the three response types. (3-15). | C01016 | Adult |
| Outcomes and Endpoints; Global Outcome | Pediatric Glasgow Coma Scale (PGCS) - Eye response score | Score for the participant's eye response according to the Pediatric Glasgow Coma Scale (PGCS) if the participant is under the age of 18. | C01020 | Pediatric |
| Outcomes and Endpoints; Global Outcome | Pediatric Glasgow Coma Scale (PGCS) - Motor response score | Score for the participant's motor response according to the Pediatric Glasgow Coma Scale (PGCS) if the participant is under the age of 18. | C01021 | Pediatric |
| Outcomes and Endpoints; Global Outcome | Pediatric Glasgow Coma Scale (PGCS) - Verbal response score | Score for the participant's verbal response according to the Pediatric Glasgow Coma Scale (PGCS) if the participant is under the age of 18. | C01022 | Pediatric |
| Outcomes and Endpoints; Global Outcome | Pediatric Glasgow Coma Scale (PGCS) - Total score | Score for the participant's total Pediatric Glasgow Coma Scale (PGCS) score of the 3 tests, eye, motor, and verbal responses. A score of less than 9 would indicate that that participant is in a severe coma while a score of greater than 9 is a mild or no coma at all. | C01017 | Pediatric |
| Outcomes and Endpoints; Global Outcome | Pediatric Glasgow Outcome Scale - Extended (GOS-E Peds) - Score | Score for the participant, as a part of the Pediatric Glasgow Outcome Scale - Extended (PGOSE). | C07434 | Pediatric |