Traumatic Brain Injury CDE Revision History Document

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May 2018 Revisions
- Biomechanical Devices Revisions
  - Blast Exposure CRF Revisions
    - C56808 (Blast sensor distribution code) - Input restrictions were corrected to Single Pre-Defined Value Selected from Free-Form Entry, as there are PVs associated with the CDE.

April 2018 Revisions
- Biomechanical Devices Revisions
  - Video Device Confirmation CRF Revisions
    - An additional reference was added to the Video Device Confirmation CRF. The new and existing references on the CRF were added to the CDE details.

March 2018 Revisions
- Biomechanical Devices Revisions
  - Head Kinematics Estimates CRF Revisions
    - C57014 (Angular sensor direct measurement type) - CDE name, variable name, definition, PVs, and suggested question text were revised. Check box for PV was incorrectly placed, which made other attributes incorrect. Revisions shown in table below:

<table>
<thead>
<tr>
<th></th>
<th>Original</th>
<th>Modification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CDE Name</strong></td>
<td>Sensor direct measure angular velocity measurement type</td>
<td>Angular sensor direct measurement type</td>
</tr>
<tr>
<td><strong>Variable Name</strong></td>
<td>SnsrDrctMsrAngVlcMsrTyp</td>
<td>AngSnsrDrctMsrTyp</td>
</tr>
<tr>
<td><strong>Definition</strong></td>
<td>Type of unit the sensor directly measures angular velocity in</td>
<td>Type of measurement done by the angular sensor</td>
</tr>
<tr>
<td><strong>PVs</strong></td>
<td>radians per second</td>
<td>angular acceleration radians per second</td>
</tr>
<tr>
<td><strong>Suggested Question Text</strong></td>
<td>Does sensor directly measure angular velocity in:</td>
<td>Does sensor directly measure:</td>
</tr>
</tbody>
</table>

- C56885 (Head accelerometer sample rate value) and C56890 (Gyroscope sample rate value) - “If sensors have different sample rates” was moved to disease
specific instructions. Suggested question text in the CDE Details did not match the CRF.

- C56897 (Data transform sensor coordinate system definition text) - "If no," was added to suggested question text in the CDE Details. Question on CRF includes this text.

  - Video Device Confirmation CRF Revisions

  - C56798 (Video device true positive impact count) and C56799 (Video device false positive count) - Disease specific instructions in the CDE Details and on the CRF were updated to reflect question number changes; max. allowable delta T is no longer question 14.

  - C56801 (Video device false negative count) - Disease specific instructions in the CDE Details do not include a question number for max. allowable delta T but CRF does. This was revised as question numbering changed.

February 2018 Revisions

- Recommendations developed by the Biomechanical Devices in Traumatic Brain Injury (TBI) Working Group were posted under the TBI data standards page: https://commondataelements.ninds.nih.gov/TBI.aspx#tab=Data_Standards

- Summaries for each of the three subgroups, Head Accelerometry, Impact Video and Blast Exposure, were added.

- Three new case report forms (CRFs) were added to the newly created Biomechanical Devices subdomain under the Disease/Injury Events domain: Head Kinematic Estimates, Video Sensor Confirmation and Blast Exposure.

- The TBI Start-up Document was updated to include these new recommendations.

June 2017 Revisions

- The Sport-Related Concussion (SRC) CDEs were posted to the NINDS website under their own landing page: https://www.commondataelements.ninds.nih.gov/SRC.aspx#tab=Data_Standards

February 2017 Revisions

- Remove the sub-domain recommendations for “Sport-Related Studies” within the Traumatic Brain Injury (TBI) version 2.0 CDEs. Four instruments under this domain were removed to alleviate confusion with the comprehensive Sports-Related Concussion CDEs, version 1.0 released in March 2017.

May 2016 Revisions

- Education year count was removed as a General Core NINDS CDE. The Oversight Committee voted to classify the CDE was Supplemental-Highly Recommended for TBI.
May 2015 Revisions

- CDEs revised for Patient Health Questionnaire -9 (PHQ-9).
- Change of the CDE names from PHQ-9 to PHQ since there are various other permutations (PHQ-8, PHQ-4 and PHQ-2) and have instructions indicating that those specific questions are part of the 9-item depression module (PHQ-9). We would prefer this than to making duplicate CDEs because they are part of the whole PHQ. This is a clear example of how data collection and metadata are different. PHQ-9 CDEs should be tagged as appropriate for the data collection but the metadata should be the same (same CDE ID and PVs). Issues of scoring are something the database should deal with separately from the metadata. The meaning (metadata) of these questions are the same.

1. Title from PHQ-9 to PHQ
2. Add instructions:
   “This question is part of the 9-item depression module (PHQ-9).”

<table>
<thead>
<tr>
<th>CdeId</th>
<th>CdeName</th>
<th>Definition</th>
<th>PVs</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>C00015</td>
<td>Education year count</td>
<td>Number of years of education completed (age 5 and beyond)</td>
<td>0;1;2;3</td>
<td>1. General Core Classification changed to Supplemental-Highly-Recommended</td>
</tr>
<tr>
<td>C07435</td>
<td>Patient Health Questionnaire (PHQ) - Abnormal diet score</td>
<td>Score of how much the subject has been bothered by abnormal diet/appetite in the past two weeks, as part of the Patient Health Questionnaire (PHQ).</td>
<td>0;1;2;3</td>
<td>1. Title from PHQ-9 to PHQ</td>
</tr>
</tbody>
</table>

2. Add instructions:
   “This question is part of the 9-item depression module (PHQ-9).”
<table>
<thead>
<tr>
<th>CdeId</th>
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<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>C07439</td>
<td>Patient Health Questionnaire (PHQ) - Better dead thought score</td>
<td>Score of how much the subject has been suffering with the thoughts of that he/she would be better off dead to hurt, as part of the Patient Health Questionnaire (PHQ).</td>
<td>0;1;2;3;</td>
<td>1. Title from PHQ-9 to PHQ 2. Add instructions: “This question is part of the 9-item depression module (PHQ-9).”</td>
</tr>
<tr>
<td>C07437</td>
<td>Patient Health Questionnaire (PHQ) - Concentration impairment score</td>
<td>Score of how much the subject has been bothered with troubling concentrating in the past two weeks, as part of the Patient Health Questionnaire (PHQ).</td>
<td>0;1;2;3;</td>
<td>1. Title from PHQ-9 to PHQ 2. Add instructions: “This question is part of the 9-item depression module (PHQ-9).”</td>
</tr>
<tr>
<td>C07431</td>
<td>Patient Health Questionnaire (PHQ) - Depressed score</td>
<td>Score of how much the subject has been feeling down and depressed in the past two weeks, as part of the Patient Health Questionnaire (PHQ).</td>
<td>0;1;2;3;</td>
<td>1. Title from PHQ-9 to PHQ 2. Add instructions: “This question is part of the 9-item depression module (PHQ-9).”</td>
</tr>
<tr>
<td>C07441</td>
<td>Patient Health Questionnaire (PHQ) - Difficulty performing scale</td>
<td>The scale related to how difficult it is to do work, take care of things at home, or get along with other people for the subject, as part of the Patient Health Questionnaire (PHQ).</td>
<td>Extremely difficult;Not difficult at all;Somewhat difficult;Very difficult;</td>
<td>1. Title from PHQ-9 to PHQ 2. Add instructions: “This question is part of the 9-item depression module (PHQ-9).”</td>
</tr>
<tr>
<td>CdeId</td>
<td>CdeName</td>
<td>Definition</td>
<td>PVs</td>
<td>Change</td>
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</tbody>
</table>
| C07436 | Patient Health Questionnaire (PHQ) - Feeling failure score              | Score of how much the subject has been feeling bad for himself/herself in the past two weeks, as part of the Patient Health Questionnaire (PHQ).                                                           | 0;1;2;3; | 1. Title from PHQ-9 to PHQ  
2. Add instructions:  
“This question is part of the 9-item depression module (PHQ-9).”                                                                                                                                                                   |
| C07430 | Patient Health Questionnaire (PHQ) - Little interest score              | Score of how much the subject has been bothered by having little interest or pleasure in doing things in the past two weeks, as part of the Patient Health Questionnaire (PHQ).                                     | 0;1;2;3; | 1. Title from PHQ-9 to PHQ  
2. Add instructions:  
“This question is part of the 9-item depression module (PHQ-9).”                                                                                                                                                                   |
| C07438 | Patient Health Questionnaire (PHQ) - Movement speech impairment score   | Score of how much the subject has been suffering with moving or speaking too slowly in the past two weeks, as part of the Patient Health Questionnaire (PHQ).                                                  | 0;1;2;3; | 1. Title from PHQ-9 to PHQ  
2. Add instructions:  
“This question is part of the 9-item depression module (PHQ-9).”                                                                                                                                                                   |
| C07432 | Patient Health Questionnaire (PHQ) - Sleep impairment score             | Score of how much the subject has been bothered with troubling falling/staying asleep or sleeping too much in the past two weeks, as part of the Patient Health Questionnaire (PHQ).                                         | 0;1;2;3; | 1. Title from PHQ-9 to PHQ  
2. Add instructions:  
“This question is part of the 9-item depression module (PHQ-9).”                                                                                                                                                                   |
<table>
<thead>
<tr>
<th>CdeId</th>
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<th>Definition</th>
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<th>Change</th>
</tr>
</thead>
</table>
| C07433 | Patient Health Questionnaire (PHQ) - Tired little energy score           | Score of how much the subject has been feeling tired in the past two weeks, as part of the Patient Health Questionnaire (PHQ).           | 0;1;2;3; | 1. Title from PHQ-9 to PHQ  
|        |                                                                          |                                                                                                                                            |       | 2. Add instructions: “This question is part of the 9-item depression module (PHQ-9).”                                           |
| C07440 | Patient Health Questionnaire Depression (PHQ-9) - Questionnaire total score | Total score of the questionnaire, as the part of Patient Health Questionnaire Depression (PHQ-9).                                          |       | 1. Title from PHQ-9 to PHQ  
|        |                                                                          |                                                                                                                                            |       | 2. Add instructions: “This question is part of the 9-item depression module (PHQ-9).”                                           |

- CDEs drafted for TBI multidimensional Quality of Life (TBI-QOL).
- UDEs drafted for Pittsburgh Sleep Quality Index (PSQI) addendum for post-traumatic stress disorder (PTSD).

**April 2015 Revisions**
- Updated Screening for TBI in Military Personnel document to remove reference to Brief TBI Screen, as the latter was not recommended by the TBI committee.
- Corrected the name of the Neurological Outcome Scale for Traumatic Brain Injury from Neurophysical Outcome Scale (NOS).
- Standardized and updated TBI ver. 1 Pediatric WG roster report.
- Unique data elements (UDE) drafted for Grooved Pegboard Test.

**March 2015 Revisions**
- Corrections to NOCs listed on the TBI page to reflect correct classifications.
- Including the addition of 63 new NOCs in TBI to match what is recommended.
<table>
<thead>
<tr>
<th>Name</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance Error Scoring System Modified</td>
<td>New NOC</td>
</tr>
<tr>
<td>Block Design Measure for Children-IV/ Wechsler Preschool and Primary Scale of Intelligence (WISC-IV/WPPSI-III)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Child Behavior Checklist (CBCL) for Ages 1.5 to 5 Years</td>
<td>New NOC</td>
</tr>
<tr>
<td>Child Behavior Checklist (CBCL) Problem Behaviors subscale</td>
<td>New NOC</td>
</tr>
<tr>
<td>Child Behavior Checklist: Social Competence Scale</td>
<td>New NOC</td>
</tr>
<tr>
<td>Child Behaviors Checklist (CBCL) Teacher Report Form</td>
<td>New NOC</td>
</tr>
<tr>
<td>Children’s Affective Lability Scale (CALS)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Children’s Motivation Scale (CMS)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Children’s Orientation and Amnesia Test (COAT)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Color-Word Interference Test Delis-Kaplan Executive Function System® (D-KEFS)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Conflict Behavior Questionnaire/Interaction Behavior Questionnaire</td>
<td>New NOC</td>
</tr>
<tr>
<td>Digit Span Subtest</td>
<td>New NOC</td>
</tr>
<tr>
<td>Dizziness Handicap Inventory (DHI)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Family History Research Diagnostic Criteria</td>
<td>New NOC</td>
</tr>
<tr>
<td>Functional Independence Measure - Cognition Subscale (Cog-FIM)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Functional Independence Measure (FIM) - Motor Subscale</td>
<td>New NOC</td>
</tr>
<tr>
<td>Functional Independence Measure for Children (WeeFIM)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Functional Independence Measure for Children (WeeFIM) - Motor Subscale</td>
<td>New NOC</td>
</tr>
<tr>
<td>Language Sample</td>
<td>New NOC</td>
</tr>
<tr>
<td>Letter-Number Sequencing Subtest</td>
<td>New NOC</td>
</tr>
<tr>
<td>National Adult Reading Test</td>
<td>New NOC</td>
</tr>
<tr>
<td>Neurological Outcome Scale for Traumatic Brain Injury (NOS-TBI)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Neuropsychiatric Rating Schedule (NRS)</td>
<td>New NOC</td>
</tr>
<tr>
<td>NIH Resources TBI Guidelines</td>
<td>New NOC</td>
</tr>
<tr>
<td>NIH Toolbox Cognitive Battery</td>
<td>New NOC</td>
</tr>
<tr>
<td>NIH Toolbox Dynamic Visual Acuity Test (DVA)</td>
<td>New NOC</td>
</tr>
<tr>
<td>NIH Toolbox Emotional Battery</td>
<td>New NOC</td>
</tr>
<tr>
<td>Test Name</td>
<td>Status</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>NIH Toolbox Hearing Handicap Inventory Supplemental Measure (HHI-SM)</td>
<td>New NOC</td>
</tr>
<tr>
<td>NIH Toolbox Motor Battery</td>
<td>New NOC</td>
</tr>
<tr>
<td>NIH Toolbox Odor Identification Test (OIT)</td>
<td>New NOC</td>
</tr>
<tr>
<td>NIH Toolbox Regional Taste Intensity Test</td>
<td>New NOC</td>
</tr>
<tr>
<td>NIH Toolbox Sensory Battery</td>
<td>New NOC</td>
</tr>
<tr>
<td>NIH Toolbox Standing Balance Test (SBT)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Patient-Reported Outcomes Measurement Information System (PROMIS), Mobility and upper extremity domains</td>
<td>New NOC</td>
</tr>
<tr>
<td>Pediatric Evaluation of Disability Inventory (PEDI) - Mobility subscale</td>
<td>New NOC</td>
</tr>
<tr>
<td>Pediatric Evaluation of Disability Inventory (PEDI): Social Functioning Scale</td>
<td>New NOC</td>
</tr>
<tr>
<td>Pediatric Quality of Life Inventory Generic Core Scale (PEDSQL Generic Core Scale)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Pediatric Quality of Life Inventory: Social Subscale</td>
<td>New NOC</td>
</tr>
<tr>
<td>Percentage of Consonants Correct-Revised (PCC-R)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Post-Concussion Symptom Inventory (PCSI)</td>
<td>New NOC</td>
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<tr>
<td>Processing Speed Index of the Wechsler Intelligence Scale for Children-IV/ Wechsler Preschool and Primary Scale of Intelligence (WISC-IV/WPPSI-III)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Processing Speed Index Subtest of the Wechsler Adult Intelligence Scale-Fourth Edition (WAIS-IV)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Shape School</td>
<td>New NOC</td>
</tr>
<tr>
<td>Short Mood and Feelings Questionnaire (SMFQ)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Strengths and Difficulties Questionnaire (SDQ)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Strengths and Difficulties Questionnaire (SDQ), Peer Relations and Pro-Social Behavior Subscales</td>
<td>New NOC</td>
</tr>
<tr>
<td>Test of Everyday Attention for Children (TEA-Ch)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Test of Strategic Learning (TOSL)</td>
<td>New NOC</td>
</tr>
<tr>
<td>The Eriksen Flanker Test</td>
<td>New NOC</td>
</tr>
<tr>
<td>Tinnitus Functional Index (TFI)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Tinnitus Handicap Inventory (THI)</td>
<td>New NOC</td>
</tr>
<tr>
<td>Trail Making Test (TMT)</td>
<td>New NOC</td>
</tr>
<tr>
<td>TRAILS-P</td>
<td>New NOC</td>
</tr>
</tbody>
</table>
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<thead>
<tr>
<th>CdeName</th>
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<th>Change</th>
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</thead>
<tbody>
<tr>
<td>Verbal Fluency Delis-Kaplan Executive Function System™ (D-KEFS)</td>
<td>New NOC</td>
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<tr>
<td>Video Social Inference Test (VSIT)</td>
<td>New NOC</td>
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<td></td>
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<tr>
<td>Vineland-II Socialization Scale</td>
<td>New NOC</td>
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<tr>
<td>Voice Handicap Index (VHI)</td>
<td>New NOC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wechsler Abbreviated Scale of Intelligence (WASI II); 2 Subtest Version</td>
<td>New NOC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wechsler Abbreviated Scale of Intelligence(R) - Second Edition (WASI-II)</td>
<td>New NOC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Word Reading Subtest of the Wide Range Achievement Test (WRAT-4)</td>
<td>New NOC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Words-In-Noise Test (WIN)</td>
<td>New NOC</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Updated TBI Roster to include Dr. Patrick Bellgowan under the TBI CDE Project Team.
- Revised Galveston Orientation and Amnesia Test (GOAT) CDEs posted.

<table>
<thead>
<tr>
<th>CdeId</th>
<th>CdeName</th>
<th>Definition</th>
<th>PVs</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>C07178</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Born date score</td>
<td>Scored ability to accurately state date of birth, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;4;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
<tr>
<td>C07181</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Building location score</td>
<td>Scored ability to accurately identify the building they are currently located, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;5;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
<tr>
<td>C07180</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - City location score</td>
<td>Scored ability to accurately name the city the subject is currently located, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;5;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
<tr>
<td>CdeId</td>
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<td>PVs</td>
<td>Change</td>
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<tr>
<td>C07189</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Day month score</td>
<td>Scored ability to identify the current day of the month, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;1;2;3;4;5;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
<tr>
<td>C07188</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Day week score</td>
<td>Scored ability to identify the current day of the week, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;1;2;3;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
<tr>
<td>C20334</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Error sum value</td>
<td>Galveston Orientation and Amnesia Test (GOAT) sum of errors score</td>
<td>New</td>
<td>(Levin et al. 1979)</td>
</tr>
<tr>
<td>C07177</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Full name score</td>
<td>Scored ability to accurately state first and last name, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;2;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
<tr>
<td>C07182</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Hospital admittance date score</td>
<td>Scored ability to accurately identify hospital admittance date, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;5;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
<tr>
<td>CdeId</td>
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<tr>
<td>C07179</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Live location score</td>
<td>Scored ability to accurately state place of residence, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;4;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
<tr>
<td>C07183</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Mode of transportation score</td>
<td>Scored ability to accurately identify the mode of transportation to the hospital, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;5;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
<tr>
<td>C07190</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Month score</td>
<td>Scored ability to identify the current month, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;10;15;5;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
<tr>
<td>C07185</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Post injury event detail score</td>
<td>Scored ability to identify the detail of the first event the subject can remember after the accident, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;5;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
<tr>
<td>C07184</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Post injury event score</td>
<td>Scored ability to provide specific details about the first event after injury, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;5;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
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<tr>
<td>C20333</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Pre injury event detail score</td>
<td>Scored ability to provide specific details about the last event before injury, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;5;</td>
<td>New</td>
</tr>
<tr>
<td>C07186</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Pre injury event score</td>
<td>Scored ability to accurately recall the last event before injury, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;5;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
<tr>
<td>C07187</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Time score</td>
<td>Scored ability to identify the current time, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;1;2;3;4;5;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
<tr>
<td>C07192</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Total score</td>
<td>Total score, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td></td>
<td>Minor revisions to question text to match original instrument text. (Levin et al. 1979)</td>
</tr>
<tr>
<td>C07191</td>
<td>The Galveston Orientation and Amnesia Test (GOAT) - Year identification score</td>
<td>Scored ability to identify the current year, as part of the Galveston Orientation and Amnesia Test (GOAT).</td>
<td>0;10;20;30;</td>
<td>Minor revisions to question text to match original instrument text. (Levin et al 1979)</td>
</tr>
</tbody>
</table>

- Revised Glasgow Outcome Scale Extended (GOS-E) CDEs posted to match:

<table>
<thead>
<tr>
<th>CdeId</th>
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</thead>
<tbody>
<tr>
<td>C20336</td>
<td>Glasgow Outcome Scale Extended (GOS-E) Supplemental Questions - Epileptic fit post injury indicator</td>
<td>Indicator if the participant has had epileptic fits since the injury as part of Glasgow Outcome Scale Extended (GOS-E) supplemental questions.</td>
<td>No;Yes;</td>
<td>New</td>
</tr>
<tr>
<td>C20337</td>
<td>Glasgow Outcome Scale Extended (GOS-E) Supplemental Questions - Epileptic fit risk indicator</td>
<td>Indicator if the participant has been told he/she is at risk of developing epilepsy as part of Glasgow Outcome Scale Extended (GOS-E) supplemental questions.</td>
<td>No;Yes;</td>
<td>New</td>
</tr>
<tr>
<td>C18412</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Assistance daily need indicator</td>
<td>Indicator if the participant needs another person at home essentially every day for some activities of daily living as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No;Yes;</td>
<td>Minor revisions to question text to match original instrument text.</td>
</tr>
<tr>
<td>C18420</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Assistance daily need pre-injury indicator</td>
<td>Indicator if the assistance at home was essential for the patient before the injury, as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No;Yes;</td>
<td>Minor revisions to question text to match original instrument text.</td>
</tr>
<tr>
<td>C18413</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Consciousness indicator</td>
<td>Indicator if participant is able to obey simple commands or say any words as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No;Yes;</td>
<td>Minor revisions to question text to match original instrument text.</td>
</tr>
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<tr>
<td>C18414</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Current other problem indicator</td>
<td>Indicator if participant faces any other current problems currently due to injury as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No;Yes;</td>
<td>Minor revisions to question text to match original instrument text.</td>
</tr>
<tr>
<td>C18415</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Current work normal capacity indicator</td>
<td>Indicator if participant is currently able to work at the same capacity before injury as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No;Yes;</td>
<td>Minor revisions to question text to match original instrument text.</td>
</tr>
<tr>
<td>C18429</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Date time</td>
<td>Date and time when Glasgow Outcome Scale Extended (GOS-E) (1-8) was administered.</td>
<td></td>
<td>Minor revisions to question text to match original instrument text.</td>
</tr>
<tr>
<td>C18410</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Extent relationship strain frequency</td>
<td>Frequency of the extent of the rifts in relationships, including family and friendships, due to psychological problems as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>Constant (daily and intolerable);Frequent (once a week or more, but tolerable);Occasional (less than weekly);</td>
<td>Minor revisions to question text to match original instrument text.</td>
</tr>
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<tr>
<td>C18416</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Extent restriction social leisure activity frequency</td>
<td>Frequency of the extent of restriction the participant faces on social and leisure activities as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>Participate a bit less: at least half as often as before injury; Participate much less: less than half as often; Unable to participate: rarely, if ever, take part;</td>
<td>Minor revisions to question text to match original instrument text.</td>
</tr>
<tr>
<td>C18418</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Frequent help need indicator</td>
<td>Indicator if the participant needs frequent help of someone to be around at home as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No; Yes;</td>
<td>Minor revisions to question text to match original instrument text.</td>
</tr>
<tr>
<td>C18411</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Outcome factor most important type</td>
<td>The most important factor in outcome as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>A mixture of these; Effects of head injury; Effects of illness or to another part of the body;</td>
<td>Minor revisions to question text to match original instrument text.</td>
</tr>
<tr>
<td>C18417</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Participation social leisure activity pre-injury indicator</td>
<td>Indicator if the extent of restriction in regular social and leisure activities outside home faced by the participant represents a change in respect of pre-injury as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No; Yes;</td>
<td>Minor revisions to question text to match original instrument text.</td>
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<tr>
<td>C18419</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Relationship disruption indicator</td>
<td>Indicator if the participant faces any rifts in family relationships or friendships caused by psychological problems as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No;Yes;</td>
<td>New</td>
</tr>
<tr>
<td>C18422</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Relationship disruption pre-injury level indicator</td>
<td>Indicator if the level of disruption or strain in family and friendships depicts a change in respect to pre-injury situation as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No;Yes;</td>
<td>Minor revisions to question text to match original instrument text.</td>
</tr>
<tr>
<td>C20335</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Respondent type</td>
<td>Person responding to the Glasgow Outcome Scale Extended (GOSE)</td>
<td>Patient alone; Patient plus relative/friend/caretaker; Relative/friend/caretaker alone;</td>
<td>New</td>
</tr>
<tr>
<td>C07194</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - score</td>
<td>Glasgow Outcome Scale Extended (1-8)</td>
<td>1;2;3;4;5;6;7;8;</td>
<td>Minor revisions to question text to match original instrument text.</td>
</tr>
<tr>
<td>C18423</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Shop without assistance indicator</td>
<td>Indicator if participant is able to shop without assistance as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No;Yes;</td>
<td>Minor revisions to question text to match original instrument text.</td>
</tr>
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<tr>
<td>C18430</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Shop without assistance pre-injury indicator</td>
<td>Indicator if participant could shop without assistance before injury as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No;Yes;</td>
<td></td>
</tr>
<tr>
<td>C18424</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Similar problems pre-injury indicator</td>
<td>Indicator if the similar problems were present before injury and have these become markedly worse as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No;Yes;</td>
<td></td>
</tr>
<tr>
<td>C18425</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Social leisure outside resume activity indicator</td>
<td>Indicator if participant could resume regular social and leisure activities outside home as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No;Yes;</td>
<td></td>
</tr>
<tr>
<td>C18426</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Travel without assistance indicator</td>
<td>Indicator if participant could travel locally without help as part of Glasgow Outcome Scale Extended (GOS-E)</td>
<td>No;Yes;</td>
<td></td>
</tr>
<tr>
<td>C18427</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Travel without assistance pre-injury indicator</td>
<td>Indicator if the participant could travel locally without help before injury as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No;Yes;</td>
<td></td>
</tr>
</tbody>
</table>
### Traumatic Brain Injury CDE Revision History Document

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<tbody>
<tr>
<td>C18428</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Work restriction from injury type</td>
<td>Work restriction type experienced by the participant as a result of injury as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>Able to work only in a sheltered workshop or non-competitive job or currently unable to work; Reduced work capacity;</td>
<td></td>
</tr>
<tr>
<td>C18421</td>
<td>Glasgow Outcome Scale Extended (GOS-E) - Work restriction pre-injury change level indicator</td>
<td>Indicator if the participant was either working or seeking employment before the injury or was doing neither, as part of Glasgow Outcome Scale Extended (GOS-E).</td>
<td>No; Yes;</td>
<td></td>
</tr>
</tbody>
</table>

- CDEs drafted for Neurological Outcome Scale for TBI.

### February 2015 Revisions

- Revised 36-Item Short Form Health Survey (SF-36) CDEs posted (minor changes).
- CDEs made for Pittsburgh Sleep Quality Index.

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>C20354</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Cannot breathe comfortably past month scale</td>
<td>The scale to which the subject had trouble breathing comfortably during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20355</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Feel too hot past month scale</td>
<td>The scale to which the subject felt too hot during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
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<tr>
<td>C20356</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Fall asleep past month minute scale</td>
<td>The scaled duration of time (in minutes) it takes the subject to fall asleep the majority of the nights in the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20357</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Sleep efficiency scale</td>
<td>The sleep efficiency scale calculated, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20358</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Awaken bathroom use past month scale</td>
<td>The scale to which the subject had to get up to use the bathroom during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20359</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Feel cold past month scale</td>
<td>The scale to which the subject felt too cold during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20360</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Pain past month scale</td>
<td>The scale to which the subject had pain during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20361</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Partner report long pause breathe while asleep past month scale</td>
<td>The scale to which the subject's partner reported long pauses between breaths during sleep the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20362</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Partner report other restlessness while asleep past month scale</td>
<td>The scale to which the subject's partner reported other restlessness during sleep past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20363</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Awaken during night early morning past month scale</td>
<td>The scale to which the subject woke up in the middle of the night or early morning during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
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<tr>
<td>C20364</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Bad dream past month scale</td>
<td>The scale to which the subject had bad dreams during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20365</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Cough snore loudly past month scale</td>
<td>The scale to which the subject coughed or snored loudly during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20366</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Trouble stay awake past month scale</td>
<td>The scale to which the subject had trouble staying awake while driving, eating meals, or engaging in social activity past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20367</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Partner report loud snore past month scale</td>
<td>The scale to which the subject's partner reported loud snoring during sleep the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20368</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Partner report episode disorientation confusion past month scale</td>
<td>The scale to which the subject's partner reported disorientation or confusion during sleep past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20369</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Other reason past month scale</td>
<td>The scale to which the subject had trouble sleeping for other reasons during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20370</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Sleep medication past month scale</td>
<td>The scale of medication use to help sleep (prescribed or 'over the counter') past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20371</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Partner report leg twitch jerk past month scale</td>
<td>The scale to which the subject's partner reported leg twitching or jerking during sleep past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
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<tr>
<td>C20372</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Sleep quality past month scale</td>
<td>Rating of overall sleep quality past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20373</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Problem maintain enthusiasm past month category</td>
<td>The scale to which the subject had problems keeping up enough enthusiasm to get things done past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20374</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Other reason other text</td>
<td>The free-text related to 'PSQIOtherRsnPastMonthRt' specifying other text</td>
<td></td>
<td>New</td>
</tr>
<tr>
<td>C20375</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Total score</td>
<td>The total score, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td></td>
<td>New</td>
</tr>
<tr>
<td>C20376</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Awaken past month time</td>
<td>The wake up time (recorded as 24-hour clock or military time) for the majority of the mornings in the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td></td>
<td>New</td>
</tr>
<tr>
<td>C20377</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Bed past month time</td>
<td>The bed time (recorded as 24-hour clock or military time) for the majority of the nights in the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td></td>
<td>New</td>
</tr>
<tr>
<td>C20378</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Actual sleep past month hour scale</td>
<td>The scaled duration (in hours) of actual sleep per night in the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
</tr>
<tr>
<td>C20379</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Partner report other restlessness while asleep past month scale other text</td>
<td>The free-text related to 'PSQIPrtnrRprtOthRestPastMoScl' specifying other text</td>
<td></td>
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</table>
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<tr>
<td>C20380</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Bed partner roommate presence scale</td>
<td>The scale that reflects the presence of a bed partner or roommate, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
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<td>C20381</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Fall asleep past month minute duration</td>
<td>The duration of time (in minutes) it takes the subject to fall asleep the majority of the nights in the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>New</td>
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<td>C20382</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Sleep disturbance scale</td>
<td>The scale to which sleep disturbance was calculated, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
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<td>C20383</td>
<td>RETIRED Pittsburgh Sleep Quality Index (PSQI) - Sleep disturbance scale</td>
<td>REDIRECTED to C20382 – Pittsburgh Sleep Quality Index (PSQI) - Sleep disturbance scale</td>
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<td>C20384</td>
<td>Pittsburgh Sleep Quality Index (PSQI) - Sleep latency scale</td>
<td>The scale to which sleep latency was calculated, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
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<td>Pittsburgh Sleep Quality Index (PSQI) - Day dysfunction due to sleepiness scale</td>
<td>The scale to which day dysfunction due to sleepiness was calculated, as part of the Pittsburgh Sleep Quality Index (PSQI).</td>
<td>0;1;2;3;</td>
<td>New</td>
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### January 2015 Revisions
- UDEs drafted for CAGE Substance Abuse Screening Tool.
- CDEs drafted for Wechsler Test of Adult Reading (WTAR).
- UDEs drafted for Orientation Log.

### November 2014 Revisions
No changes.

### September 2014 Revisions
No changes.
August 2014 Revisions
No changes.

July 2014 Revisions
No changes.

June 2014 Revisions
- Upload of various CRFs and NOCs in TBI with editorial corrections.

May 2014 Revisions
No changes.

April 2014 Revisions
No changes.

March 2014 Revisions
- Updates to TBI Publications.

February 2014 Revisions
No changes.

January 2014 Revisions
- Screening Tools for Hearing, Tinnitus, Balance, Taste/Smell, and Speech/Swallowing loaded for TBI.
- Brief Symptom Inventory – 18 loaded for TBI.
- Race/Ethnicity CDEs modified to meet the needs of the International TBI group.

December 2013 Revisions
- Addition of the American Congress of Rehabilitation Medicine (ACRM) support letter in TBI.
- New start-up resource for TBI.
- Change in text of Update tab for TBI.

November 2013 Revisions
No changes.

October 2013 Release

Overview
There have been changes to the content and structure of the TBI CDE materials in version 2.0 compared to version 1.0 including the following:
Form Status Changes

New Forms:

- Short Form-36 (SF-36)
- Pediatric Quality of Life Inventory (PedsQL)
- Pediatric Test of Brain Injury (PTBI)
- Short Form-12 Health Survey (SF-12)
- Child Behavior Checklist (CBCL)
- Comprehensive Test of Phonological Processing (CTOPP)
- Gray Oral Reading Test, 4th Edition (GORT-4)
- KeyMath-3 Diagnostic Assessment
- Test of Word Reading Efficiency (TOWRE)
- Woodcock-Johnson, 3rd Edition (WJ-III)
- Adaptive Behavior Assessment System (ABAS-II)
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- The National Institute of Health (NIH) Toolbox
- Random-Gap Detection Test
- SCAN-A and SCAN-C Auditory Processing Disorders Subtests
- Time-Compressed Sentence Test
- Victoria Symptom Validity Test
- Test of Memory Malingering (TOMM)
- Medical Symptom Validity Test (MVST)
Word Memory Test

Child and Adolescent Scale of Environment (CASE)

Family Burden of Injury Interview

EuroQol-5 Dimension Questionnaire (EQ-5D)

Bayley Scales of Infant and Toddler Development-III

Brief Infant Toddler Social Emotional Assessment (BITSEA)

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California Verbal Learning Test for Children (CVLT-C)

Conner’s Continuous Performance Test-Revised (CPT-2)

Contingency Naming Test (CNT)
Controlled Oral Word Association Test (COWAT)

Delis-Kaplan Executive Functioning System (DKEFS)-Trail Making Tests

Functional Assessment of Verbal Reasoning and Executive Strategies – Student Version (FAVRES-S)

Grooved Pegboard Test

Rey Auditory Verbal Learning Test (RAVLT)

Test of Memory and Learning-Revised (TOMAL-2)

Wechsler Adult Intelligence Scale-4th Edition (WAIS-IV)

Wide Range of Achievement Test (WRAT-4)

Wide Range Assessment of Memory and Learning 2nd Edition (WRAML-2)

Patient Reported Outcomes Measurement Information System (PROMIS)

Quality of Life in Neurological Disorders (Neuro-Qol)

Quality of Life after Brain Injury (QOLIBRI)

Bruininks-Oseretsky Test of Motor Proficiency-2 (BOT-2)

The Rivermead Post-Concussive Symptom Questionnaire (RPQ)

Brief Symptom Inventory – 18 Item (BSI-18)

Clinician-Administered PTSD Scale (CAPS)

Minnesota Multiphasic Personality Inventory – 2 – Restructured Form (MMPI-2-RF)

Modified Overt Aggression Scale (MOAS)

Screen for Child Anxiety Related Emotional Disorders (SCARED)

The UCLA PTSD Index for the DSM-IV

Interpersonal Negotiations Strategies (INS)

Reading the Mind in the Eyes Test-Child Version

Social Skills Rating Scale (SSRS)

Axon Sports Computerized Cognitive Assessment Tool (CCAT)

CNS Vital Signs
Updated Forms:

Notice of Copyright Created (NOC) (Will replace previously existing forms)

Screening for TBI in Military Personnel

Disability Rating Scale (DRS)

Glasgow Outcome Scale (GOS)

Glasgow Outcome Scale Extended (GOSE)

Glasgow Outcome Scale Extended (GOSE) Pediatric Revision

Mayo-Portland Adaptability Inventory-4 (MPAI-4)

Family Assessment Device

Sexual Satisfaction Scale

Military Acute Concussion Evaluation (MACE)

Satisfaction with Life Scale (SWLS)

Health and Behavior Inventory

Health and Behavior Inventory (HBI) Parent Current Version

Health and Behavior Inventory (HBI) Parent Retrospective Version

Neurobehavioral Symptom Inventory

Alcohol Use Disorders Identification Test: Self-Report Version (AUDIT)

Alcohol, Smoking, and Substance Use Involvement Screening Test (ASSIST)

Center for Epidemiologic Studies-Depression Scale (CES-D)

Patient Health Questionnaire - 9 (PHQ-9)

PTSD Checklist - Civilian (PCL-C)

PTSD Checklist - Military (PCL-M)
Traumatic Brain Injury CDE Revision History Document

PTSD Checklist - Stressor Specific (PCL-S)

Substance Abuse Questions from the TBI Model Systems Database

Galveston Orientation and Amnesia Test (GOAT)

JFK Coma Recovery Scale- Revised

Craig Handicap and Assessment Reporting Technique (CHART-SF)

Participation Assessment with Recombined Tools (PART-O)

**Removed Forms:**

None

**Detailed Form Revisions:**

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

### 1 Traumatic Brain Injury Revision History Table

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Traumatic Brain Injury CDE Revision History Document

April 2013 Release

Overview
There have been minor changes to the content and structure of the TBI CDE materials including the following:

Form Status Changes
New Forms:
- None

Updated Forms:
- Notice of Copyright Created (NOC) (Will replace previously existing forms)
  - Ohio State University TBI Identification Form

Removed Forms:
- None

Detailed Form Revisions:
Additional specific changes to the CRF modules are detailed in the table included on the subsequent table.

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October 2012 Release

Overview
There have been significant changes to the content and structure of the TBI CDE materials in Version 2.0 compared to Version 1.0, including the following:

- Every attempt was made to remove duplication and redundancy in the TBI CDEs;
- The TBI CDEs were harmonized with other large national and international standardization initiatives and efforts [e.g., International Conference on Harmonisation (ICH), Logical...
The majority of element names and definitions were improved and the permissible values and references of some elements were revised;

The CDEs were reorganized according to type of TBI study (Concussion/mild TBI studies, Acute Hospitalized studies, Moderate/Severe TBI: Rehabilitation studies, and Epidemiology studies); and finally,

The number of “Core” CDEs, strongly recommended for all NINDS-funded studies, was reduced.

The corresponding data dictionaries (i.e., CDE Detailed Report) have been modified in accordance with the form changes.

Form Status Changes

New Forms:

Case report form templates were created and added to this Web site rather than just referring users to the IMPACT Web site

- Demographics
- Socioeconomic Status
- Significant Medical History
- Injury Presentation - Early/Late
- Type, Place, Cause and Mechanism of Injury
- Injuries and Injury Severity
- Second Insults and Other Complications
- Discharge Status
- ER Destination
- Neurological Assessment: Glasgow Coma Scale (GCS) and Pupils
- Neurological Assessment: LOC, PTA, and AOC
- Neurological Assessment: TBI Symptoms and Signs
- Vital Signs and Blood Gases
- Laboratory Tests
- Imaging
- ER/Admission Therapeutic Procedures
Traumatic Brain Injury CDE Revision History Document

- Post Discharge/Outpatient Treatment
- Informed Consent
- Post Discharge Status
- Death

**Removed Forms:**
- None

**Detailed Form Revisions:**

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

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<td>Modified CDE(s)</td>
<td>Nearly all CDE names and definitions were updated to achieve greater consistency across all NINDS CDEs and for clarity</td>
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<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>Modified CDE(s)</td>
<td>CDEs were reorganized by four types of studies (Concussion/mild TBI studies, Acute Hospitalized studies, Moderate/Severe TBI: Rehabilitation studies, and Epidemiology studies) and were also classified as Core, Basic, or Supplemental by study type.</td>
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<td>Minor</td>
<td>New form(s)</td>
<td>CRF templates were created using the Core and Basic CDEs for the following modules: Demographics; Socioeconomic Status; Significant Medical History; Injury Presentation - Early/Late; Type, Place, Cause and Mechanism of Injury; Injuries and Injury Severity; Second Insults and Other Complications; Discharge Status; ER Destination; Neurological Assessment: Glasgow Coma Scale (GCS) and Pupils; Neurological Assessment: LOC, PTA, and AOC; Neurological Assessment: TBI Symptoms and Signs; Vital Signs and Blood Gases; Laboratory Tests; Imaging; ER/Admission Therapeutic Procedures; Post Discharge/Outpatient Treatment; Informed Consent; Post Discharge Status; and Death</td>
</tr>
<tr>
<td>Various</td>
<td>2.0</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified form(s)</td>
<td>The following modifications were made to the modules: Separate modules for adult and pediatric were merged; &quot;Post Discharge Outpatient Treatment&quot; was split into &quot;Post-Discharge Status&quot; and &quot;Post Discharge Outpatient Treatment&quot;; &quot;ABC and Vital Signs on Admission&quot; and &quot;Vital Signs and Blood Gases- Daily/Hourly&quot; were merged into one &quot;Vital Signs and Blood Gases&quot; module; Additional edits made to module names, placement in domains/subdomains, and associated CDEs</td>
</tr>
<tr>
<td>Various</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>Modified CDE(s)</td>
<td>Many CDE codes, definitions for codes, data types, instructions, and references were modified</td>
</tr>
<tr>
<td>Various</td>
<td>2.0</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified CDE(s)</td>
<td>The population information for many CDEs was modified (i.e., the CDEs were labeled as appropriate for use in adults, pediatrics, or both adults and pediatrics).</td>
</tr>
<tr>
<td>CRF Module/ Guideline</td>
<td>Current Version</td>
<td>Previous Version</td>
<td>Change Classification</td>
<td>Change Type</td>
<td>Description of Change</td>
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</tr>
<tr>
<td>Various</td>
<td>2.0</td>
<td>1.0</td>
<td>Minor</td>
<td>Deleted</td>
<td>The following types of CDEs were deleted: CDEs redundant with other CDEs, including repeated adult/pediatric CDEs and CDEs repeated at multiple timepoints; CDEs specifying unit; CDEs specifying an &quot;other, specify&quot; response; and several derived elements.</td>
</tr>
<tr>
<td>Demographics</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New</td>
<td>The following CDE(s) were added: Language primary ISO 639-2 code; Language spoken fluently ISO 639-2 code; Language written fluently ISO 639-2 code; Birth country ISO 3166-1 alpha-2 code</td>
</tr>
<tr>
<td>Socioeconomic Status</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New</td>
<td>The following CDE(s) were added: Education level primary caregiver USA type; Family income supported persons number; Family income range; Military service status; Health insurance type</td>
</tr>
<tr>
<td>Behavioral History</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New</td>
<td>The following CDE(s) were added: Alcohol use last month days drank number; Alcohol use last month drinking day average drinks number; Alcohol use last month consumed more than four or five drinks days number; Alcohol prior use indicator</td>
</tr>
<tr>
<td>Significant Medical History</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New</td>
<td>The following CDE(s) were added: Head injury prior number; Medical history condition SNOMED CT code</td>
</tr>
<tr>
<td>Ohio State University TBI Identification Method Short Form</td>
<td>2.0</td>
<td>1.0</td>
<td>Minor</td>
<td>Modified form(s)</td>
<td>CDEs from the structural interview were deleted; scoring CDEs were added.</td>
</tr>
<tr>
<td>Type, Place, Cause and Mechanism of Injury</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New</td>
<td>The following CDE(s) were added: Injury ICD-9-CM external cause code</td>
</tr>
<tr>
<td>Injuries and Injury Severity</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New</td>
<td>The following CDE(s) were added: Spine injury anatomic site</td>
</tr>
<tr>
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</tr>
<tr>
<td>Discharge Status</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New CDE(s)</td>
<td>The following CDE(s) were added: Definitive clinical care location type</td>
</tr>
<tr>
<td>Neurological Assessment: Neuroworsening</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>Deleted CDE(s)</td>
<td>All CDEs associated with the &quot;Neurological Assessment: Neuroworsening&quot; module were deleted.</td>
</tr>
<tr>
<td>Vital Signs and Other Body Measures</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New CDE(s)</td>
<td>The following CDE(s) were added: Respiratory support type</td>
</tr>
<tr>
<td>Laboratory Tests</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New CDE(s)</td>
<td>The following CDE(s) were added: Alcohol blood test performed indicator; Lab test LOINC code; Lab test result unit of measure UCUM code; Lab test result status; Lab test abnormality significance type</td>
</tr>
<tr>
<td>Imaging</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New CDE(s)</td>
<td>The following CDE(s) were added: Brain imaging result; Diffuse axonal injury and traumatic axonal injury lesions number; Intraventricular hemorrhage pattern type</td>
</tr>
<tr>
<td>Prior and Concomitant Medications</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New CDE(s)</td>
<td>The following CDE(s) were added: Medication prior or concomitant RXNorm code; Medication prior or concomitant dose unit of measure UCUM code</td>
</tr>
<tr>
<td>ER/Admission Therapeutic Procedures</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New CDE(s)</td>
<td>The following CDE(s) were added: Intracranial procedures indicator</td>
</tr>
<tr>
<td>Surgical and Therapeutic Procedures</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New CDE(s)</td>
<td>The following CDE(s) were added: Surgical or therapeutic procedure ICD-9-CM code</td>
</tr>
<tr>
<td>Intraoperative Management</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New CDE(s)</td>
<td>The following CDE(s) were added: Advanced Surgical Associates standard monitors used type; Volatile or intravenous anesthesia indicator; Arterial line indicator; Foley catheter indicator; Transfusion indicator; Transfusion type; End of case extubated indicator; Microdialysis glutamate value; Microdialysis lactate to pyruvate ratio value; Cerebral spinal fluid drainage indicator</td>
</tr>
<tr>
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</tr>
<tr>
<td>Post Discharge/Outpatient Treatment</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New CDE(s)</td>
<td>The following CDE(s) were added: Therapy or rehabilitation ICD-9-CM code</td>
</tr>
<tr>
<td>Various Modules in the Outcomes and End Points Domain</td>
<td>2.0</td>
<td>1.0</td>
<td>Major</td>
<td>New CDE(s)</td>
<td>Additional outcome measures were recommended, including: Medical Symptom Validity Test; Test of Memory Malingering (TOMM); Victoria Symptom Validity Test; Word Memory Test; Family History Research Diagnostic Criteria (FHRDC); Short Form-12 Health Survey (SF-12); Combat Exposure Scale (CES); Military Acute Concussion Evaluation; Veterans Rand 36 Item Health Survey (VR-36); Symbol Digit Modalities Test; Automated Neuropsychological Assessment Metrics (ANAM); Balance Error Scoring System (Modified); Neuropsychiatric Rating Schedule (NPRS); Beck Depression Inventory - 2 (BDI-2); Center for Epidemiologic Studies Depression Scale (CES-D); Patient Health Questionnaire (9 Item) (PHQ-9); Clinician-Administered PTSD Scale (CAPS); Immediate Post-Concussion Assessment and Cognitive Testing (imPACT); Sport Concussion Assessment Tool (SCAT-2); Axon Sports Computerized Cognitive Assessment Tool (CCAT); CNS Vital Signs; Headminder Concussion Resolution Index; Brief Test of Adult Cognition by Telephone; Bedside Western Aphasia Battery - Revised; National Adult Reading Test; Wechsler Test of Adult Reading</td>
</tr>
</tbody>
</table>

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