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January 2020 Revisions

- General Core CRF updated to replace 'Gender' question with 'Sex assigned at birth' and 'Gender identity'.
- Two new CDEs added to CRF: C58676 (Sex assigned at birth) and C58677 (Gender identity).
 C00035 has been removed
- Start-Up document updated to reflect these changes.

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. New Reference: Kuo C, Wu LC, Loza J, Senif D, Anderson S, Camarillo DB. Comparison of video-based and sensor-based head impact exposure. bioRxiv 235432. 2017. doi: https://doi.org/10.1101/235432
 Existing Reference: Cortes N, Lincoln AE, Myer GD, Hepburn L, Higgins M, Putukian M. Video Analysis Verification of Head Impact Events Measured by Wearable Sensors. American Journal of Sports Medicine. 2017;45:2379-2387.

March 2018 Revisions

- Biomechanical Devices Revisions
 - o 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:

	Original	Modification
CDE Name	Sensor direct measure angular	Angular sensor direct
CDE Name	velocity measurement type	measurement type

Variable Name	SnsrDrctMsrAngVlcMsrTyp	AngSnsrDrctMsrTyp	
Definition	Type of unit the sensor directly measures angular velocity in	Type of measurement done by the angular sensor	
PVs	radians per second	angular acceleration radians per second	
Suggested Question Text	Does sensor directly measure angular velocity in:	Does sensor directly measure:	

- 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.
- o 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:<u>https://commondataelements.ninds.nih.gov/TBI.aspx#tab=Data_Standards</u>
- 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.

Cdeld	CdeName	Definition	PVs	Change
C00015	Education year count	Number of years of education completed (age 5 and beyond)	0;1;2;3;	1. General Core Classification changed to Supplemental-Highly- Recommended

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)."

Cdeld	CdeName	Definition	PVs	Change
C07435	Patient Health Questionnaire (PHQ) - Abnormal diet score	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).	0;1;2;3;	 Title from PHQ-9 to PHQ Add instructions: "This question is part of the 9-item depression module (PHQ-9)."
C07439	Patient Health Questionnaire (PHQ) - Better dead thought score	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).	0;1;2;3;	 Title from PHQ-9 to PHQ Add instructions: "This question is part of the 9-item depression module (PHQ-9)."
C07437	Patient Health Questionnaire (PHQ) - Concentration impairment score	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).	0;1;2;3;	 Title from PHQ-9 to PHQ Add instructions: "This question is part of the 9-item depression module (PHQ-9)."
C07431	Patient Health Questionnaire (PHQ) - Depressed score	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).	0;1;2;3;	 Title from PHQ-9 to PHQ Add instructions: "This question is part of the 9-item depression module (PHQ-9)."

CdeId	CdeName	Definition	PVs	Change
C07441	Patient Health Questionnaire (PHQ) - Difficulty performing scale	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).	Extremely difficult;Not difficult at all;Somewhat difficult;Very difficult;	 Title from PHQ-9 to PHQ Add instructions: "This question is part of the 9-item depression module (PHQ-9)."
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;	 Title from PHQ-9 to PHQ 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;	 Title from PHQ-9 to PHQ 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;	 Title from PHQ-9 to PHQ Add instructions: "This question is part of the 9-item depression module (PHQ-9)."

Cdeld	CdeName	Definition	PVs	Change
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;	 Title from PHQ-9 to PHQ Add instructions: "This question is part of the 9-item depression module (PHQ-9)."
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;	 Title from PHQ-9 to PHQ 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).		 Title from PHQ-9 to PHQ 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.

Name	Change
Balance Error Scoring System Modified	New NOC
Block Design Measure for Children-IV/ Wechsler Preschool and Primary Scale of Intelligence (WISC-IV/WPPSI-III)	New NOC
Child Behavior Checklist (CBCL) for Ages 1.5 to 5 Years	New NOC
Child Behavior Checklist (CBCL) Problem Behaviors subscale	New NOC
Child Behavior Checklist: Social Competence Scale	New NOC
Child Behaviors Checklist (CBCL) Teacher Report Form	New NOC
Children's Affective Lability Scale (CALS)	New NOC
Children's Motivation Scale (CMS)	New NOC
Children's Orientation and Amnesia Test (COAT)	New NOC
Color-Word Interference Test Delis-Kaplan Executive Function System [®] (D-KEFS)	New NOC
Conflict Behavior Questionnaire/Interaction Behavior Questionnaire	New NOC
Digit Span Subtest	New NOC
Dizziness Handicap Inventory (DHI)	New NOC
Family History Research Diagnostic Criteria	New NOC
Functional Independence Measure - Cognition Subscale (Cog-FIM)	New NOC
Functional Independence Measure (FIM) - Motor Subscale	New NOC
Functional Independence Measure for Children (WeeFIM)	New NOC
Functional Independence Measure for Children (WeeFIM) - Motor Subscale	New NOC
Language Sample	New NOC
Letter-Number Sequencing Subtest	New NOC
National Adult Reading Test	New NOC
Neurological Outcome Scale for Traumatic Brain Injury (NOS-TBI)	New NOC
Neuropsychiatric Rating Schedule (NRS)	New NOC
NIH Resources TBI Guidelines	New NOC
NIH Toolbox Cognitive Battery	New NOC
NIH Toolbox Dynamic Visual Acuity Test (DVA)	New NOC
NIH Toolbox Emotional Battery	New NOC

NIH Toolbox Hearing Handicap Inventory Supplemental Measure (HHI-SM)	New NOC
NIH Toolbox Motor Battery	New NOC
NIH Toolbox Odor Identification Test (OIT)	New NOC
NIH Toolbox Regional Taste Intensity Test	New NOC
NIH Toolbox Sensory Battery	New NOC
NIH Toolbox Standing Balance Test (SBT)	New NOC
Patient-Reported Outcomes Measurement Information System (PROMIS), Mobility and upper extremity domains	New NOC
Peabody Developmental Motor Scales 2nd-Edition (PDMS-2)	New NOC
Pediatric Evaluation of Disability Inventory (PEDI) - Mobility subscale	New NOC
Pediatric Evaluation of Disability Inventory (PEDI): Social Functioning Scale	New NOC
Pediatric Quality of Life Inventory Generic Core Scale (PEDSQL Generic Core Scale)	New NOC
Pediatric Quality of Life Inventory: Social Subscale	New NOC
Percentage of Consonants Correct-Revised (PCC-R)	New NOC
Post-Concussion Symptom Inventory (PCSI)	New NOC
Processing Speed Index of the Wechsler Intelligence Scale for Children-IV/ Wechsler Preschool and Primary Scale of Intelligence (WISC-IV/WPPSI-III)	New NOC
Processing Speed Index Subtest of the Wechsler Adult Intelligence Scale-Fourth Edition (WAIS-IV)	New NOC
Shape School	New NOC
Short Mood and Feelings Questionnaire (SMFQ)	New NOC
Strengths and Difficulties Questionnaire (SDQ)	New NOC
Strengths and Difficulties Questionnaire (SDQ), Peer Relations and Pro-Social Behavior Subscales	New NOC
Test of Everyday Attention for Children (TEA-Ch)	New NOC
Test of Strategic Learning (TOSL)	New NOC
The Eriksen Flanker Test	New NOC
Tinnitus Functional Index (TFI)	New NOC
Tinnitus Handicap Inventory (THI)	New NOC
Trail Making Test (TMT)	New NOC
TRAILS-P	New NOC

Traumatic Brain Injury Multidimensional Quality of Life (TBI-QOL)	New NOC
Verbal Fluency Delis-Kaplan Executive Function System™ (D-KEFS)	New NOC
Video Social Inference Test (VSIT)	New NOC
Vineland-II Socialization Scale	New NOC
Voice Handicap Index (VHI)	New NOC
Wechsler Abbreviated Scale of Intelligence (WASI II); 2 Subtest Version	New NOC
Wechsler Abbreviated Scale of Intelligence(R) - Second Edition (WASI-II)	New NOC
Word Reading Subtest of the Wide Range Achievement Test (WRAT-4)	New NOC
Words-In-Noise Test (WIN)	New NOC

• Updated TBI Roster to include Dr. Patrick Bellgowan under the TBI CDE Project Team.

Cdeld	CdeName	Definition	PVs	Change
C07178	The Galveston Orientation and Amnesia Test (GOAT) - Born date score	Scored ability to accurately state date of birth, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;4;	Minor revisions to question text to match original instrument text. (Levin et al. 1979)
C07181	The Galveston Orientation and Amnesia Test (GOAT) - Building location score	Scored ability to accurately identify the building they are currently located, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;5;	Minor revisions to question text to match original instrument text. (Levin et al. 1979)
C07180	The Galveston Orientation and Amnesia Test (GOAT) - City location score	Scored ability to accurately name the city the subject is currently located, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;5;	Minor revisions to question text to match original instrument text. (Levin et al. 1979)

• Revised Galveston Orientation and Amnesia Test (GOAT) CDEs posted.

	Child Change Definition					
Cdeld	CdeName	Definition	PVs	Change		
C07189	The Galveston Orientation and Amnesia Test (GOAT) - Day month score	Scored ability to identify the current day of the month, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;1;2;3;4;5;	Minor revisions to question text to match original instrument text. (Levin et al. 1979)		
C07188	The Galveston Orientation and Amnesia Test (GOAT) - Day week score	Scored ability to identify the current day of the week, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;1;2;3;	Minor revisions to question text to match original instrument text. (Levin et al. 1979)		
C20334	The Galveston Orientation and Amnesia Test (GOAT) - Error sum value	Galveston Orientation and Amnesia Test (GOAT) sum of errors score		New (Levin et al. 1979)		
C07177	The Galveston Orientation and Amnesia Test (GOAT) - Full name score	Scored ability to accurately state first and last name, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;2;	Minor revisions to question text to match original instrument text. (Levin et al. 1979)		
C07182	The Galveston Orientation and Amnesia Test (GOAT) - Hospital admittance date score	Scored ability to accurately identify hospital admittance date, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;5;	Minor revisions to question text to match original instrument text. (Levin et al. 1979)		

CdeId	CdeName	Definition	PVs	Change
C07179	The Galveston Orientation and Amnesia Test (GOAT) - Live location score	Scored ability to accurately state place of residence, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;4;	Minor revisions to question text to match original instrument text. (Levin et al. 1979)
C07183	The Galveston Orientation and Amnesia Test (GOAT) - Mode of transportation score	Scored ability to accurately identify the mode of transportation to the hospital, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;5;	Minor revisions to question text to match original instrument text. (Levin et al. 1979)
C07190	The Galveston Orientation and Amnesia Test (GOAT) - Month score	Scored ability to identify the current month, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;10;15;5;	Minor revisions to question text to match original instrument text. (Levin et al. 1979)
C07185	The Galveston Orientation and Amnesia Test (GOAT) - Post injury event detail score	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).	0;5;	Minor revisions to question text to match original instrument text. (Levin et al. 1979)
C07184	The Galveston Orientation and Amnesia Test (GOAT) - Post injury event score	Scored ability to provide specific details about the first event after injury, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;5;	Minor revisions to question text to match original instrument text. (Levin et al. 1979)

Cdeld	CdeName	Definition	PVs	Change
C20333	The Galveston Orientation and Amnesia Test (GOAT) - Pre injury event detail score	Scored ability to provide specific details about the last event before injury, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;5;	New
C07186	The Galveston Orientation and Amnesia Test (GOAT) - Pre injury event score	Scored ability to accurately recall the last event before injury, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;5;	Minor revisions to question text to match original instrument text. (Levin et al. 1979)
C07187	The Galveston Orientation and Amnesia Test (GOAT) - Time score	Scored ability to identify the current time, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;1;2;3;4;5;	Minor revisions to question text to match original instrument text. (Levin et al. 1979)
C07192	The Galveston Orientation and Amnesia Test (GOAT) - Total score	Total score, as part of the Galveston Orientation and Amnesia Test (GOAT).		Minor revisions to question text to match original instrument text. (Levin et al. 1979)
C07191	The Galveston Orientation and Amnesia Test (GOAT) - Year identification score	Scored ability to identify the current year, as part of the Galveston Orientation and Amnesia Test (GOAT).	0;10;20;30;	Minor revisions to question text to match original instrument text. (Levin et al 1979)

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

Wilson JTL, Pettigrew LEL, Teasdale GM. Structured interviews for the Glasgow Outcome Scale and the Extended Glasgow Outcome Scale: Guidelines for their use. J Neurotrauma 1998;15:573–585.

Cdeld	CdeName	Definition	PVs	Change
C20336	Glasgow Outcome Scale Extended (GOS - E) Supplemental Questions - Epileptic fit post injury indicator	Indicator if the participant has had epileptic fits since the injury as part of Glasgow Outcome Scale Extended (GOS- E) supplemental questions.	No;Yes;	New
C20337	Glasgow Outcome Scale Extended (GOS - E) Supplemental Questions - Epileptic fit risk indicator	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.	No;Yes;	New
C18412	Glasgow Outcome Scale Extended (GOS-E) - Assistance daily need indicator	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).	No;Yes;	Minor revisions to question text to match original instrument text.
C18420	Glasgow Outcome Scale Extended (GOS-E) - Assistance daily need pre- injury indicator	Indicator if the assistance at home was essential for the patient before the injury, as part of Glasgow Outcome Scale Extended (GOS-E).	No;Yes;	Minor revisions to question text to match original instrument text.
C18413	Glasgow Outcome Scale Extended (GOS-E) - Consciousness indicator	Indicator if participant is able to obey simple commands or say any words as part of Glasgow Outcome Scale Extended (GOS-E).	No;Yes;	Minor revisions to question text to match original instrument text.

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CdeId	CdeName	Definition	PVs	Change
C18414	Glasgow Outcome Scale Extended (GOS-E) - Current other problem indicator	Indicator if participant faces any other current problems currently due to injury as part of Glasgow Outcome Scale Extended (GOS-E).	No;Yes;	Minor revisions to question text to match original instrument text.
C18415	Glasgow Outcome Scale Extended (GOS-E) - Current work normal capacity indicator	Indicator if participant is currently able to work at the same capacity before injury as part of Glasgow Outcome Scale Extended (GOS-E).	No;Yes;	Minor revisions to question text to match original instrument text.
C18429	Glasgow Outcome Scale Extended (GOS-E) - Date time	Date and time when Glasgow Outcome Scale Extended (GOS-E) (1-8) was administered.		Minor revisions to question text to match original instrument text.
C18410	Glasgow Outcome Scale Extended (GOS-E) - Extent relationship strain frequency	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).	Constant (daily and intolerable);Frequent (once a week or more, but tolerable);Occasional (less than weekly);	Minor revisions to question text to match original instrument text.

Cdeld	CdeName	Definition	PVs	Change
C18416	Glasgow Outcome Scale Extended (GOS-E) - Extent restriction social leisure activity frequency	Frequency of the extent of restriction the participant faces on social and leisure activities as part of Glasgow Outcome Scale Extended (GOS-E).	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;	Minor revisions to question text to match original instrument text.
C18418	Glasgow Outcome Scale Extended (GOS-E) - Frequent help need indicator	Indicator if the participant needs frequent help of someone to be around at home as part of Glasgow Outcome Scale Extended (GOS-E).	No;Yes;	Minor revisions to question text to match original instrument text.
C18411	Glasgow Outcome Scale Extended (GOS-E) - Outcome factor most important type	The most important factor in outcome as part of Glasgow Outcome Scale Extended (GOS-E).	A mixture of these;Effects of head injury;Effects of illness or to another part of the body;	Minor revisions to question text to match original instrument text.
C18417	Glasgow Outcome Scale Extended (GOS-E) - Participation social leisure activity pre- injury indicator	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).	No;Yes;	Minor revisions to question text to match original instrument text.

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Cdeld	CdeName	Definition	PVs	Change
C18419	Glasgow Outcome Scale Extended (GOS-E) - Relationship disruption indicator	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).	No;Yes;	New
C18422	Glasgow Outcome Scale Extended (GOS-E) - Relationship disruption pre- injury change level indicator	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).	No;Yes;	Minor revisions to question text to match original instrument text.
C20335	Glasgow Outcome Scale Extended (GOS-E) - Respondent type	Person responding to the Glasgow Outcome Scale Extended (GOSE)	Patient alone;Patient plus relative/friend/caretaker; Relative/friend/caretaker alone;	New
C07194	Glasgow Outcome Scale Extended (GOS-E) - score	Glasgow Outcome Scale Extended (1-8)	1;2;3;4;5;6;7;8;	Minor revisions to question text to match original instrument text.
C18423	Glasgow Outcome Scale Extended (GOS-E) - Shop without assistance indicator	Indicator if participant is able to shop without assistance as part of Glasgow Outcome Scale Extended (GOS-E).	No;Yes;	Minor revisions to question text to match original instrument text.

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CdeId	CdeName	Definition	PVs	Change
C18430	Glasgow Outcome Scale Extended (GOS-E) - Shop without assistance pre- injury indicator	Indicator if participant could shop without assistance before injury as part of Glasgow Outcome Scale Extended (GOS-E).	No;Yes;	
C18424	Glasgow Outcome Scale Extended (GOS-E) - Similar problems pre- injury indicator	Indicator if the similar problems were present before injury and have these become markedly worse as part of Glasgow Outcome Scale Extended (GOS- E).	No;Yes;	
C18425	Glasgow Outcome Scale Extended (GOS-E) - Social leisure outside resume activity indicator	Indicator if participant could resume regular social and leisure activities outside home as part of Glasgow Outcome Scale Extended (GOS-E).	No;Yes;	
C18426	Glasgow Outcome Scale Extended (GOS-E) - Travel without assistance indicator	Indicator if participant could travel locally without help as part of Glasgow Outcome Scale Extended (GOS-E)	No;Yes;	
C18427	Glasgow Outcome Scale Extended (GOS-E) - Travel without assistance pre- injury indicator	Indicator if the participant could travel locally without help before injury as part of Glasgow Outcome Scale Extended (GOS-E).	No;Yes;	

CdeId	CdeName	Definition	PVs	Change
C18428	Glasgow Outcome Scale Extended (GOS-E) - Work restriction from injury type	Work restriction type experienced by the participant as a result of injury as part of Glasgow Outcome Scale Extended (GOS-E).	Able to work only in a sheltered workshop or non-competitive job or currently unable to work;Reduced work capacity;	
C18421	Glasgow Outcome Scale Extended (GOS-E) - Work restriction pre- injury change level indicator	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).	No;Yes;	

• 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.

Cdeld	CdeName	Definition	PVs	Change
C20354	Pittsburgh Sleep Quality Index (PSQI) - Cannot breathe comfortably past month scale	The scale to which the subject had trouble breathing comfortably during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New
C20355	Pittsburgh Sleep Quality Index (PSQI) - Feel too hot past month scale	The scale to which the subject felt too hot during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New

Cdeld	CdeName	Definition	PVs	Change
C20356	Pittsburgh Sleep Quality Index (PSQI) - Fall asleep past month minute scale	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).	0;1;2;3;	New
C20357	Pittsburgh Sleep Quality Index (PSQI) - Sleep efficiency scale	The sleep efficiency scale calculated, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New
C20358	Pittsburgh Sleep Quality Index (PSQI) - Awaken bathroom use past month scale	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).	0;1;2;3;	New
C20359	Pittsburgh Sleep Quality Index (PSQI) - Feel cold past month scale	The scale to which the subject felt too cold during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New
C20360	Pittsburgh Sleep Quality Index (PSQI) - Pain past month scale	The scale to which the subject had pain during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New
C20361	Pittsburgh Sleep Quality Index (PSQI) - Partner report long pause breathe while asleep past month scale	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).	0;1;2;3;	New
C20362	Pittsburgh Sleep Quality Index (PSQI) - Partner report other restlessness while asleep past month scale	The scale to which the subject's partner reported other restlessness during sleep past month, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New
C20363	Pittsburgh Sleep Quality Index (PSQI) - Awaken during night early morning past month scale	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).	0;1;2;3;	New

Traumatic Brain Injury CDE Revision History Document
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CdeId	CdeName	Definition	PVs	Change
C20364	Pittsburgh Sleep Quality Index (PSQI) - Bad dream past month scale	The scale to which the subject had bad dreams during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New
C20365	Pittsburgh Sleep Quality Index (PSQI) - Cough snore loudly past month scale	The scale to which the subject coughed or snored loudly during the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New
C20366	Pittsburgh Sleep Quality Index (PSQI) - Trouble stay awake past month scalee	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).	0;1;2;3;	New
C20367	Pittsburgh Sleep Quality Index (PSQI) - Partner report loud snore past month scale	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).	0;1;2;3;	New
C20368	Pittsburgh Sleep Quality Index (PSQI) - Partner report episode disorientation confusion past month scale	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).	0;1;2;3;	New
C20369	Pittsburgh Sleep Quality Index (PSQI) - Other reason past month scale	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).	0;1;2;3;	New
C20370	Pittsburgh Sleep Quality Index (PSQI) - Sleep medication past month scale	The scale of medication use to help sleep (prescribed or 'over the counter') past month, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New
C20371	Pittsburgh Sleep Quality Index (PSQI) - Partner report leg twitch jerk past month scale	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).	0;1;2;3;	New

CdeId	CdeName	Definition	PVs	Change
C20372	Pittsburgh Sleep Quality Index (PSQI) - Sleep quality past month scale	Rating of overall sleep quality past month, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New
C20373	Pittsburgh Sleep Quality Index (PSQI) - Problem maintain enthusiasm past month category	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).	0;1;2;3;	New
C20374	Pittsburgh Sleep Quality Index (PSQI) - Other reason other text	The free-text related to 'PSQIOtherRsnPastMonthRt' specifying other text		New
C20375	Pittsburgh Sleep Quality Index (PSQI) - Total score	The total score, as part of the Pittsburgh Sleep Quality Index (PSQI).		New
C20376	Pittsburgh Sleep Quality Index (PSQI) - Awaken past month time	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).		New
C20377	Pittsburgh Sleep Quality Index (PSQI) - Bed past month time	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).		New
C20378	Pittsburgh Sleep Quality Index (PSQI) - Actual sleep past month hour scale	The scaled duration (in hours) of actual sleep per night in the past month, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New
C20379	Pittsburgh Sleep Quality Index (PSQI) - Partner report other restlessness while asleep past month scale other text	The free-text related to 'PSQIPrtnrRprtOthRestPastMoScl' specifying other text		New

Traumatic Brain Injury CDE Revision History Document

CdeId	CdeName	Definition	PVs	Change
C20380	Pittsburgh Sleep Quality Index (PSQI) - Bed partner roommate presence scale	The scale that reflects the presence of a bed partner or roommate, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New
C20381	Pittsburgh Sleep Quality Index (PSQI) - Fall asleep past month minute duration	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).		New
C20382	Pittsburgh Sleep Quality Index (PSQI) - Sleep disturbance scale	The scale to which sleep disturbance was calculated, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New
C20383	RETIRED Pittsburgh Sleep Quality Index (PSQI) - Sleep disturbance scale	REDIRECTED to C20382 – Pittsburgh Sleep Quality Index (PSQI) - Sleep disturbance scale	0;1;2;3;	New
C20384	Pittsburgh Sleep Quality Index (PSQI) - Sleep latency scale	The scale to which sleep latency was calculated, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New
C20385	Pittsburgh Sleep Quality Index (PSQI) - Day dysfunction due to sleepiness scale	The scale to which day dysfunction due to sleepiness was calculated, as part of the Pittsburgh Sleep Quality Index (PSQI).	0;1;2;3;	New

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) Pediatric Evaluation of Disability Inventory (PEDI) Vineland Adaptive Behavior Scales, 2nd Edition (VABS-II) Frontal Systems Behavior Scale (FrSBe) Brief Test of Adult Cognition by Telephone (BTACT) National Health and Nutrition Examination Chemical Senses-Taste and Smell Questionnaire (NHANES CSQ) 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) **TBI Revision History Document Version 3.1**

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) Mullen Scales of Early Learning (MSEL) Bedside Western Aphasia Battery - Revised Caregiver Unintelligible Speech Rating Scale Clinical Evaluation of Language Fundamentals (CELF-4) Comprehensive Assessment of Spoken Language (CASL) Goldman-Fristoe Test of Articulation-2 (GTFA-2) Peabody Picture Vocabulary Test, 4th Edition (PPVT-4) Test of Language Competence-Expanded (TLCE) Verbal Motor Production Assessment for Children (VMPAC) Wechsler Abbreviated Scale of Intelligence (WASI) Wechsler Test of Adult Reading (WTAR) The Combat Exposure Scale (CES) Veterans Rand 36 Item Health Survey (VR-36) Automated Neuropsychological Assessment Metrics (ANAM) Beery-Buktenica Developmental Test of Visual-Motor Integration, 6th edition (Beery VMI) Brief Visuospatial Memory Test – Revised (BVMT-R) 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

Headminder Concussion Resolution Index Immediate Post-Concussion Assessment and Cognitive Testing (imPACT) Sport Concussion Assessment Tool (SCAT-2) **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)

TBI Revision History Document Version 3.1

PTSD Checklist - Military (PCL-M)

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

CRF Module/	Current	Previous	Change	Change Type	Description of
Guideline	Version	Version	Classification		Change
Short Form-36 (SF-	2.0	1.0	Major	Notice of	A Notice of
36)				Copyright	Copyright was
					created for
					this form and
					will replace
					the existing
					form
Pediatric Quality of	2.0	1.0	Major	Notice of	A Notice of
Life Inventory				Copyright	Copyright was
(PedsQL)					created for
					this form and
					will replace
					the existing
					form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Pediatric Test of Brain Injury (PTBI)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Short Form-12 Health Survey (SF- 12)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Child Behavior Checklist (CBCL)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Comprehensive Test of Phonological Processing (CTOPP)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Gray Oral Reading Test, 4th Edition (GORT-4)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
KeyMath-3 Diagnostic Assessment	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Test of Word Reading Efficiency (TOWRE)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Woodcock- Johnson, 3rd Edition (WJ-III)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Adaptive Behavior Assessment System (ABAS-II)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Pediatric Evaluation of Disability Inventory (PEDI)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Vineland Adaptive Behavior Scales, 2nd Edition (VABS- II)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Frontal Systems Behavior Scale (FrSBe)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Brief Test of Adult Cognition by Telephone (BTACT)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
National Health and Nutrition Examination Chemical Senses- Taste and Smell Questionnaire (NHANES CSQ)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
The National Institute of Health (NIH) Toolbox	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Random-Gap Detection Test	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
SCAN-A and SCAN- C Auditory Processing Disorders Subtests	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Time-Compressed Sentence Test	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Victoria Symptom Validity Test	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Test of Memory Malingering (TOMM)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/	Current	Previous	Change	Change Type	Description of
Guideline	Version 2.0	Version 1.0	Classification Major	Notice of	Change A Notice of
Medical Symptom Validity Test (MVST)	2.0	1.0		Copyright	Copyright was created for this form and will replace
					the existing form
Word Memory Test	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Child and Adolescent Scale of Environment (CASE)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Family Burden of Injury Interview	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
EuroQoL-5 Dimension Questionnaire (EQ- 5D)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Bayley Scales of Infant and Toddler Development-III	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace
Brief Infant Toddler Social Emotional Assessment (BITSEA)	2.0	1.0	Major	Notice of Copyright	the existing form A Notice of Copyright was created for this form and will replace
Mullen Scales of Early Learning (MSEL)	2.0	1.0	Major	Notice of Copyright	the existing form A Notice of Copyright was created for
Bedside Western	2.0	1.0	Major	Notice of	this form and will replace the existing form A Notice of
Aphasia Battery – Revised				Copyright	Copyright was created for this form and will replace the existing form
Caregiver Unintelligible Speech Rating Scale	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/	Current	Previous	Change	Change Type	Description of
Guideline	Version	Version	Classification		Change
Clinical Evaluation of Language Fundamentals (CELF-4)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing
					form
Comprehensive Assessment of Spoken Language (CASL)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Goldman-Fristoe Test of Articulation-2 (GTFA-2)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Peabody Picture Vocabulary Test, 4th Edition (PPVT- 4)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Test of Language Competence- Expanded (TLCE)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Verbal Motor Production Assessment for Children (VMPAC)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Wechsler Abbreviated Scale of Intelligence (WASI)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Wechsler Test of Adult Reading (WTAR)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
The Combat Exposure Scale (CES)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Veterans Rand 36 Item Health Survey (VR-36)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/	Current	Previous	Change	Change Type	Description of
Guideline	Version	Version	Classification		Change
Automated Neuropsychological Assessment Metrics (ANAM)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Beery-Buktenica Developmental Test of Visual- Motor Integration, 6th edition (Beery VMI)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Brief Visuospatial Memory Test – Revised (BVMT-R)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
California Verbal Learning Test for Children (CVLT-C)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Conner's Continuous Performance Test- Revised (CPT-2)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Contingency Naming Test (CNT)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Controlled Oral Word Association Test (COWAT)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Delis-Kaplan Executive Functioning System (DKEFS)-Trail Making Tests	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Functional Assessment of Verbal Reasoning and Executive Strategies – Student Version (FAVRES-S)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Grooved Pegboard Test	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/	Current	Previous	Change	Change Type	Description of
Guideline	Version	Version	Classification		Change
Rey Auditory Verbal Learning Test (RAVLT)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Test of Memory and Learning- Revised (TOMAL-2)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Wechsler Adult Intelligence Scale- 4 th Edition (WAIS- IV)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Wide Range of Achievement Test (WRAT-4)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Wide Range Assessment of Memory and Learning 2 nd Edition (WRAML-2)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Patient Reported	2.0	1.0	Major	Notice of	A Notice of
Outcomes				Copyright	Copyright was
Measurement					created for
Information					this form and
System (PROMIS)					will replace
					the existing
					form
Quality of Life in	2.0	1.0	Major	Notice of	A Notice of
Neurological				Copyright	Copyright was
Disorders (Neuro-					created for
Qol)					this form and
					will replace
					the existing
					form
Quality of Life after	2.0	1.0	Major	Notice of	A Notice of
Brain Injury				Copyright	Copyright was
(QOLIBRI)					created for
					this form and
					will replace
					the existing
					form
Bruininks-	2.0	1.0	Major	Notice of	A Notice of
Oseretsky Test of				Copyright	Copyright was
Motor Proficiency-					created for
2 (BOT-2)					this form and
					will replace
					the existing
					form
The Rivermead	2.0	1.0	Major	Notice of	A Notice of
Post-Concussive				Copyright	Copyright was
Symptom					created for
Questionnaire					this form and
(RPQ)					will replace
					the existing
					form

CRF Module/	Current	Previous	Change	Change Type	Description of
Guideline	Version	Version	Classification		Change
Brief Symptom	2.0	1.0	Major	Notice of	A Notice of
Inventory 18				Copyright	Copyright was
ltem (BSI-18)					created for
					this form and
					will replace
					the existing
					form
Clinician-	2.0	1.0	Major	Notice of	A Notice of
Administered PTSD				Copyright	Copyright was
Scale (CAPS)					created for
					this form and
					will replace
					the existing
					form
Minnesota	2.0	1.0	Major	Notice of	A Notice of
Multiphasic				Copyright	Copyright was
Personality					created for
Inventory – 2 –					this form and
Restructured Form					will replace
(MMPI-2-RF)					the existing
					form
Modified Overt	2.0	1.0	Major	Notice of	A Notice of
Aggression Scale				Copyright	Copyright was
(MOAS)					created for
					this form and
					will replace
					the existing
					form
Screen for Child	2.0	1.0	Major	Notice of	A Notice of
Anxiety Related				Copyright	Copyright was
Emotional					created for
Disorders (SCARED)					this form and
					will replace
					the existing
					form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
The UCLA PTSD Index for the DSM- IV	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Interpersonal Negotiations Strategies (INS)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Reading the Mind in the Eyes Test- Child Version	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Social Skills Rating Scale (SSRS)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Axon Sports Computerized Cognitive Assessment Tool (CCAT)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/	Current	Previous	Change	Change Type	Description of
Guideline	Version	Version	Classification		Change
CNS Vital Signs	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Headminder Concussion Resolution Index	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Immediate Post- Concussion Assessment and Cognitive Testing (imPACT)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Sport Concussion Assessment Tool (SCAT-2)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Screening for TBI in Military Personnel	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Disability Rating Scale (DRS)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Glasgow Outcome Scale (GOS)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Glasgow Outcome Scale Extended (GOSE)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Glasgow Outcome Scale Extended (GOSE) Pediatric Revision	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Mayo-Portland Adaptability Inventory-4 (MPAI- 4)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Family Assessment Device	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Sexual Satisfaction Scale	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Military Acute Concussion Evaluation (MACE)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Satisfaction with Life Scale (SWLS)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Health and Behavior Inventory	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/	Current	Previous	Change	Change Type	Description of
Guideline	Version	Version	Classification		Change
Health and Behavior Inventory (HBI) Parent Current Version	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and
					will replace the existing form
Health and Behavior Inventory (HBI) Parent Retrospective Version	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Neurobehavioral Symptom Inventory	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Alcohol Use Disorders Identification Test: Self-Report Version (AUDIT)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Alcohol, Smoking, and Substance Use Involvement Screening Test (ASSIST)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Center for	2.0	1.0	Major	Notice of	A Notice of
Epidemiologic Studies-Depression Scale (CES-D)				Copyright	Copyright was created for this form and will replace the existing
					form
Patient Health Questionnaire - 9 (PHQ-9)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
PTSD Checklist - Civilian (PCL-C)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
PTSD Checklist - Military (PCL-M)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
PTSD Checklist - Stressor Specific (PCL-S)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Substance Abuse Questions from the TBI Model Systems Database	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Galveston Orientation and Amnesia Test (GOAT)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
JFK Coma Recovery Scale- Revised	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Craig Handicap and Assessment Reporting Technique (CHART- SF)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Participation Assessment with Recombined Tools (PART-O)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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.

2 Traumatic Brain Injury Revision History Table

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Ohio State	2.0	1.0	Major	Notice of	A Notice of
University TBI				Copyright	Copyright was
Identification					created for
Method Short					this form and
Form					will replace
					the existing
					form

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

Observation Identifiers Names and Codes (LOINC), International Classification of Diseases (ICD), Unified Code for Units of Measure (UCUM)];

- 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

- 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.

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
All	2.0	1.0	Minor	Modified CDE(s)	Nearly all CDE names and definitions were updated to achieve greater consistency across all NINDS CDEs and for clarity
All	2.0	1.0	Major	Modified CDE(s)	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.

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Various	2.0	1.0	Minor	New form(s)	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
Various	2.0	1.0	Minor	Modified form(s)	The following modifications were made to the modules: Separate modules for adult and pediatric were merged; "Post Discharge Outpatient Treatment" was split into "Post-Discharge Status" and "Post Discharge Outpatient Treatment"; "ABC and Vital Signs on Admission" and "Vital Signs and Blood Gases- Daily/Hourly" were merged into one "Vital Signs and Blood Gases" module; Additional edits made to module names, placement in domains/subdomains, and associated CDEs
Various	2.0	1.0	Major	Modified CDE(s)	Many CDE codes, definitions for codes, data types, instructions, and references were modified
Various	2.0	1.0	Minor	Modified CDE(s)	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).

CRF Module/	Current	Previous	Change	Change	Description of Change
Guideline	Version	Version	Classification	Туре	
Various	2.0	1.0	Minor	Deleted CDE(s)	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 "other, specify" response; and several derived elements.
Demographics	2.0	1.0	Major	New CDE(s)	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
Socioeconomic Status	2.0	1.0	Major	New CDE(s)	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
Behavioral History	2.0	1.0	Major	New CDE(s)	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
Significant Medical History	2.0	1.0	Major	New CDE(s)	The following CDE(s) were added: Head injury prior number; Medical history condition SNOMED CT code
Ohio State University TBI Identification Method Short Form	2.0	1.0	Minor	Modified form(s)	CDEs from the structural interview were deleted; scoring CDEs were added.
Type, Place, Cause and Mechanism of Injury	2.0	1.0	Major	New CDE(s)	The following CDE(s) were added: Injury ICD-9-CM external cause code
Injuries and Injury Severity	2.0	1.0	Major	New CDE(s)	The following CDE(s) were added: Spine injury anatomic site

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change	
Discharge Status	2.0	1.0	Major	New CDE(s)	The following CDE(s) were added: Definitive clinical care location type	
Neurological Assessment: Neuroworsening	2.0	1.0	Major	Deleted CDE(s)	All CDEs associated with the "Neurological Assessment: Neuroworsening" module were deleted.	
Vital Signs and Other Body Measures	2.0	1.0	Major	New CDE(s)	The following CDE(s) were added: Respiratory support type	
Laboratory Tests	2.0	1.0	Major	New CDE(s)	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	
Imaging	2.0	1.0	Major	New CDE(s)	The following CDE(s) were added: Brain imaging result; Diffuse axonal injury and traumatic axonal injury lesions number; Intraventricular hemorrhage pattern type	
Prior and Concomitant Medications	2.0	1.0	Major	New CDE(s)	The following CDE(s) were added: Medication prior or concomitant RXNorm code; Medication prior or concomitant dose unit of measure UCUM code	
ER/Admission Therapeutic Procedures	2.0	1.0	Major	New CDE(s)	The following CDE(s) were added: Intracranial procedures indicator	
Surgical and Therapeutic Procedures	2.0	1.0	Major	New CDE(s)	The following CDE(s) were added: Surgical or therapeutic procedure ICD- 9-CM code	
Intraoperative Management	2.0	1.0	Major	New CDE(s)	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	

	C	Drandaus	Charren	Charren	Description of Change
CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Post Discharge/Outpatient Treatment	2.0	1.0	Major	New CDE(s)	The following CDE(s) were added: Therapy or rehabilitation ICD-9-CM code
Various Modules in the Outcomes and End Points Domain	2.0	1.0	Major	New CDE(s)	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