



NINDS Common Data Element (CDE) Project

Traumatic Brain Injury Version 3.0

Internal Review / Public Review

Assessments and Examinations Subgroup Materials

Subgroup Summary

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- Glasgow Coma Scale (GCS)
- Injury Severity Score
- Ohio State University TBI Identification Method Short Form
- Pediatric Glasgow Coma Scale (pGCS)
- Pediatric Risk of Mortality Score

Case Report Forms

- Baseline Risk Assessment
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- Type, Place, Cause and Mechanism of Injury
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- Vital Signs and Blood Gases

Instruments Pending Review

- Screening for TBI in Military Personnel



NINDS CDE Project Traumatic Brain Injury Version 3.0 Assessments and Examinations Subgroup Summary

The NINDS TBI v3.0 Common Data Element (CDE) Assessments and Examinations Subgroup developed CDEs based on advancements in neuroscientific clinical research and evolving standards in clinical TBI assessment. The Assessments and Examinations Subgroup focused on identifying and defining clinical and physiological examination domains that capture the acute and subacute trajectory of TBI in both military and civilian populations, adult and pediatric. This subgroup is essential in TBI for characterizing the severity, presentation, and secondary complications of brain injury, through structured clinical observations, vital sign trends, and physiological monitoring. The subgroup did not include advanced neuroimaging, neuropsychological batteries, or long-term functional outcome measures, which fall under the scope of other designated subgroups.

The subgroup assessed a range of data collection tools, including clinician-reported case report forms (CRFs), patient screening tools, and monitoring summaries. These tools span across experimental and observational studies and include data relevant to both adult and pediatric TBI populations. CRFs reviewed include measures related to disease/injury events, injury classification, vital signs, intracranial pressure monitoring, and secondary insults. The subgroup also considered validated screening tools such as the Ohio State University TBI Identification Method Short Form and Screening for TBI in Military Personnel. The subgroup's review process followed TBI v3.0 instrument selection criteria, prioritizing measures that are feasible, reliable, clinically relevant, and harmonizable across studies and care settings.



Summary of Recommendations

Subdomain	Instrument/CRF Name	Classification	Population
Biomechanical Devices	Blast Exposure	Supplemental	Adult
	Head Kinematics Estimates	Supplemental – Highly Recommended; Supplemental	Adult; Pediatric
	Video Device Confirmation	Supplemental – Highly Recommended; Supplemental	Adult; Pediatric
Classification	Abbreviated Injury Scale	Pending Classification	
	Baseline Risk Assessment	Disease Core; Supplemental – Highly Recommended; Supplemental	Adult; Pediatric
	Glasgow Coma Scale (GCS)	Disease Core	
	Injury Severity Score	Supplemental – Highly Recommended	
	Pediatric Glasgow Coma Scale (pGCS)	Pending Classification	
	Pediatric Risk of Mortality Score	Supplemental	
History of Disease/Injury Event	Injury Presentation - Early/Late	Disease Core; Supplemental – Highly Recommended; Supplemental	Adult; Pediatric
	Ohio State University TBI Identification Method Short Form	Pending Classification	Adult; Pediatric
	Type, Place, Cause and Mechanism of Injury	Disease Core; Supplemental – Highly Recommended	Adult; Pediatric
Second Insults	Second Insults and Other Complications	Supplemental – Highly Recommended; Supplemental	Adult; Pediatric
Vital Signs and Other Body Measures	Height and Weight	Supplemental	Adult; Pediatric
	Intracranial Pressure (ICP) Monitoring	Supplemental	Adult; Pediatric
	Vital Signs and Blood Gases	Supplemental	Adult; Pediatric

CRFs Reviewed and Not Recommended for v3.0

CRF Name	TBI v2.0 Classification
Injuries and Injury Severity	Basic; Supplemental

Instruments Pending Review for v3.0

Instrument Name	TBI v2.0 Classification
Screening for TBI in Military Personnel	Supplemental

NINDS CDE Notice of Copyright Abbreviated Injury Scale (New for TBI)

Availability	Please visit this website for more information about the instrument: Abbreviated Injury Scale
Classification TBI v3.0 Classification Pending	
Short Description of Instrument	The Abbreviated Injury Scale (AIS) is an anatomical-based coding system that classifies the severity of injuries, representing the threat to life associated with the injury.
Comments/Special Instructions	The AIS measures single injuries and is the basis for the Injury Severity Score (ISS) calculation for multiple injuries.
Scoring and Psychometric Properties	<p>Scoring: The score represents three aspects of the participant's injury written as 12(34)(56).7.</p> <p>Each number represents the following:</p> <ul style="list-style-type: none"> • 1: Body region • 2: Type of anatomical structure • 3, 4: Specific anatomical structure • 5, 6: Level • 7: Severity of score <p>Psychometric Properties: Physicians and nurses tend to be more reliable in their ratings than either emergency medical technicians or nonclinical technicians. Reliability of AIS scoring was somewhat higher for blunt versus penetrating injuries (MacKenzie et al., 1985). The AIS demonstrated almost perfect reliability of AIS coders within the same trauma center, but variability across trauma centers (Gunning et al., 2023).</p>
Rationale/Justification	<p>Strengths: The AIS is one of the most common anatomic scales for traumatic injuries.</p> <p>Weaknesses: The AIS requires expert coders and is typically assigned retrospectively because AIS requires precise anatomic detail that may not be evident early on or may evolve with further imaging or surgical findings. The AIS is challenging in that it uses mild/moderate/severe terminology like current TBI classification but not with the same criteria.</p>
References	<p>Key References:</p> <p>Gennarelli, T. A. (1985). American Association for Automotive Medicine. <i>Committee on Injury Scaling. Abbreviated Injury Scale</i>. Arlington Heights, IL, USA: American Association for Automotive Medicine.</p> <p>Association for the Advancement of Automotive Medicine. (2016). <i>Abbreviated Injury Scale (c) 2005 Update 2008</i>. (T. Gennarelli, & e. Woodzin, Eds.) Chicago, Illinois.</p> <p>Association for the Advancement of Automotive Medicine. (2018). <i>Abbreviated Injury Scale: 2015 Revision</i> (6 ed.). Chicago, IL.</p> <p>Additional References:</p> <p>Loftis KL, Price J, Gillich PJ. Evolution of the Abbreviated Injury Scale: 1990-2015. <i>Traffic Inj Prev</i>. 2018;19(sup2):S109-S113.</p>

MacKenzie EJ, Shapiro S, Eastham JN. The Abbreviated Injury Scale and Injury Severity Score. Levels of inter- and intrarater reliability. Med Care. 1985 Jun;23(6):823-35.

TBI-Specific Reference(s):

Gunning AC, Niemeyer MJS, van Heijl M, van Wessem KJP, Maier RV, Balogh ZJ, Leenen LPH. Inter-rater reliability of the Abbreviated Injury Scale scores in patients with severe head injury shows good inter-rater agreement but variability between countries. An inter-country comparison study. Eur J Trauma Emerg Surg. 2023 Jun;49(3):1183-1188.

Document last updated November 2025

NINDS CDE Notice of Copyright Glasgow Coma Scale (GCS) (New for TBI)

Availability	Please visit this website for more information about the instrument: Glasgow Coma Scale
Classification	<p>Core: Traumatic Brain Injury (TBI)</p> <p>NeuroRehab Supplemental – Highly Recommended: Recommendations for Use: Indicated for studies requiring a physical/neurological examination. Recommended for Stroke studies.</p> <p>Supplemental – Highly Recommended: Stroke (based on study type, disease stage and disease type)</p>
Short Description of Instrument	The Glasgow Coma Scale (GCS) was developed to overcome the misunderstandings and confusion about comatose patients. The GCS is also used to assess neurological trauma as well as to document and predict neurological changes. It is considered the gold standard in this regard and is widely used.
Comments/Special Instructions	<p>The timing and frequency of assessment that are appropriate varies according to the stage after onset of the impairment of consciousness and the pattern in any previous observations of a patient. Observation should begin as soon as possible after onset of the impaired consciousness in order to guide initial management and to establish a baseline against which to interpret later findings. Observations initially should be repeated frequently to establish if the patient is stable or to detect any trends of improvement, or of deterioration from developing complications. When a stable pattern emerges as time passes, the frequency can be reduced.</p> <p>The scale can be applied without modification to children over 5 years old. In younger children and infants, an assessment of a verbal response as “orientated” and motor response as “obeys commands” is usually not possible. A ‘Paediatric Glasgow Coma Scale’ was therefore described in the Adelaide Coma Scale in which responses were modified.</p>
Scoring and Psychometric Properties	<p>Scoring: Three questions must be answered in regards to unconsciousness and coma with the first addressing eye opening, the second motor function and the third verbal response. Scores range from 3-15 total points with lower scores indicating patients in comatose.</p> <p>Psychometric Properties: Consistency in its findings is a key feature of a clinical assessment and during the development of the Glasgow Coma Scale it was shown to be better than existing methods. Although some subsequent studies reported levels ranging from very poor to excellent, a definitive systematic review has shown that the reproducibility of the scale is usually high.</p>
Rationale/Justification	<p>Strengths:</p> <p>Weaknesses:</p>
References	<p>Key Reference(s): Teasdale G, Jennett B. Assessment of coma and impaired consciousness. A practical scale. Lancet. 1974;2(7872):81–84.</p> <p>Additional References:</p>

	<p>Baker M. Reviewing the application of the Glasgow Coma Scale: Does it have interrater reliability? J Neurosci Nurs. 2008;4(7):342-347.</p> <p>Reith FC, Van den Brande R, Synnot A, Gruen R, Maas AI. The reliability of the Glasgow Coma Scale: a systematic review. J Intensive Care Med. 2016;42(1):3-15.</p> <p>Sternbach GL. The Glasgow coma scale. J Emerg Med. 2000;19(1):67-71.</p> <p>Teasdale G, Knill-Jones R, van der Sande J. Observer variability in assessing impaired consciousness and coma. J Neurol Neurosurg Psychiatry. 1978;41(7):603-610.</p> <p>Teasdale G, Maas A, Lecky F, Manley G, Stocchetti N, Murray G. The Glasgow Coma Scale at 40 years: standing the test of time. Lancet Neurol. 2014;13(8):844-854.</p> <p>Weir CJ, Bradford AP, Lees KR. The prognostic value of the components of the Glasgow Coma Scale following acute stroke. QJM. 2003;96(1):67-74.</p> <p>TBI-Specific References:</p> <p>Balestreri M, Czosnyka M, Chatfield DA, Steiner LA, Schmidt EA, Smielewski P, Matta B, Pickard JD. Predictive value of Glasgow Coma Scale after brain trauma: change in trend over the past ten years. J Neurol Neurosurg Psychiatry. 2004;75(1):161-162.</p> <p>Marmarou A, Lu J, Butcher I, McHugh GS, Murray GD, Steyerberg EW, Mushkudiani NA, Choi S, Maas AI. Prognostic value of the Glasgow Coma Scale and pupil reactivity in traumatic brain injury assessed pre-hospital and on enrollment: an IMPACT analysis. J Neurotrauma. 2007;24(2):270-280.</p> <p>Stocchetti N, Pagan F, Calappi E, Canavesi K, Beretta L, Citerio G, Cormio M, Colombo A. Inaccurate early assessment of neurological severity in head injury. J Neurotrauma. 2004;21(9):1131-1140.</p> <p><i>Document last updated January 2022 December 2025</i></p>
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NINDS CDE Notice of Copyright Injury Severity Score (New for TBI)

Availability	Please visit this website for more information about the instrument: Injury Severity Score
Classification	Supplemental – Highly Recommended: Traumatic Brain Injury (TBI)
Short Description of Instrument	The Injury Severity Score (ISS) is a numerical system used to assess trauma severity. The ISS correlates with mortality, morbidity, and hospitalization time after trauma. It is used to define the term major trauma (see definition in Scoring section).
Comments/Special Instructions	The Abbreviated Injury Scale (AIS) measures single injuries and is the basis for the Injury Severity Score (ISS) calculation for multiple injuries.
Scoring and Psychometric Properties	<p>Scoring: The ISS is calculated by adding the squares of the three highest AIS scores ($ISS = A^2 + B^2 + C^2$ where A, B, C are the AIS scores of the three most injured body regions). Scores range from 1 to 75. If any of the three AIS scores is 6, the ISS is automatically scored as the maximum, 75. An Injury Severity Score greater than 15 indicates a major trauma (or polytrauma).</p> <p>Psychometric Properties: There is a monotonic relationship between expected mortality and the ISS value of injuries sustained in both vehicular and nonvehicular incidents (Semmlow and Cone, 1976). “Increasing ISS is associated with increasing mortality, but the relationship is not linear” (Beverland and Rutherford, 1983).</p>
Rationale/Justification	<p>Strengths: The ISS is shown to correlate well with mortality, ICU length of stay, and resource use.</p> <p>Weaknesses: The ISS is dependent on AIS coding. The ISS has poor discrimination in certain populations and body region groupings are arbitrary. Not ideal for penetrating trauma or isolated head injuries.</p>
References	<p>Key Reference(s): Baker SP, O'Neill B, Haddon W Jr, Long WB. The injury severity score: a method for describing patients with multiple injuries and evaluating emergency care. J Trauma. 1974 Mar;14(3):187-96.</p> <p>Additional References: Beverland DE, Rutherford WH. An assessment of the validity of the injury severity score when applied to gunshot wounds. Injury. 1983 Jul;15(1):19-22.</p> <p>Copes WS, Champion HR, Sacco WJ, Lawnick MM, Keast SL, Bain LW. The Injury Severity Score revisited. J Trauma. 1988 Jan;28(1):69-77.</p> <p>Feldhaus I, Carvalho M, Waiz G, Igu J, Matthay Z, Dicker R, Juillard C. The feasibility, appropriateness, and applicability of trauma scoring systems in low and middle-income countries: a systematic review. Trauma Surg Acute Care Open. 2020 May 6;5(1):e000424.</p>

	<p>Semmlow JL, Cone R. Utility of the injury severity score: a confirmation. Health Serv Res. 1976 Spring;11(1):45-52.</p> <p>TBI-Specific Reference(s):</p> <p><i>Document last updated December 2025</i></p>
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Ohio State University TBI Identification Method Short Form

Availability	<p>Please visit this website for more information about the instrument: Ohio State University TBI Identification Method Short Form</p> <p>Freely available through the OSU website. Please be sure to use the link above when accessing the form. The Ohio State University Traumatic Brain Injury Identification Method (OSU TBI-ID) may be used free of charge and without further permission as long as no changes are made to the provided version. Versions have been developed that vary in length; the OSU TBI-ID can be adapted for specific populations and situations.</p>
Classification TBI v3.0 Classification Pending	<p>Basic: TBI Epidemiology</p> <p>Supplemental: TBI Acute Hospitalized; Concussion/Mild TBI; and Moderate/Severe TBI: Rehabilitation; Huntington's Disease (HD) and Parkinson's Disease (PD)</p>
Short Description of Instrument	<p>The OSU TBI-ID is a standardized procedure to elicit the lifetime history of TBI for an individual. The instrument is based on Center for Disease Control and Prevention (CDC; National Center for Injury Prevention and Control, 2003) case definitions and recommendations for TBI surveillance.</p> <p>Different verbiage is used when self-reporting a TBI. To avoid confusion and errors in reporting, the OSU TBI-ID first asks for recollection of all injuries that required medical attention, or that should have been treated. The OSU TBI-ID then focuses on injuries to head or neck with mechanisms involving high velocity forces. The occurrence of altered states of consciousness, the nature of the changes, and age at the time of the injury are then determined. The OSU TBI-ID provides data for calculating summary indices reflecting the likelihood that consequences have resulted from lifetime exposure to TBI. OSU TBI-ID Short Form can be used for clinical, research or programmatic purposes.</p> <p>Administration method: Interview, either by telephone or face-to-face. Administration time: Short Form is typically administered in about 5 minutes.</p>
Comments/Special Instructions	<p>The TBI identification training module may be accessed at the link above.</p>
Scoring and Psychometric Properties	<p>Scoring: Score is broken down into the following categories:</p> <p>Number of Injuries with Loss of Consciousness (LOC): Number of injuries with LOC (count total less than 30 minutes, 30 minutes to 24 hours, greater than 24 hours) Number of injuries with LOC greater than or equal to 30 minutes (count total greater than or equal to 30 minutes, greater than 24 hours)</p> <p>Age at First Injury with LOC: Age at first injury with LOC First injury with LOC occurred before age 15 (yes=1, no=0)</p>

	<p>Classifying Worst Injury: 1 = IMPROBABLE TBI – if interview all questions #1-5 are “no” or if in response to question #6, interview data reports never having LOC, being dazed or having memory lapses. 2 = POSSIBLE MILD TBI WITHOUT LOC - if in response to question #6, interview data reports being dazed or having a memory lapse 3 = MILD TBI WITH LOC - if in response to question #6, interview data reports LOC does not exceed 30 minutes for any injury 4 = MODERATE TBI - if in response to question #6, interview data reports LOC for any one injury is between 30 minutes and 24 hours 5 = SEVERE TBI - if in response to question #6, interview data reports LOC for any one injury exceeds 24 hours</p> <p>Number of Anoxic Injuries: Total the number of times with LOC due to drug overdose or being choked</p> <p><u>Interpretation of Scores:</u> The scores are indicators of lifetime exposure to TBI. The following are associated with the likelihood that the person is experiencing cognitive and behavioral consequences from the injury(s).</p> <ul style="list-style-type: none"> ○ Number of injuries: Multiple lifetime injuries (including multiple mild injuries) are associated with greater cognitive and behavioral difficulties. However, more important than the number of injuries may be whether they occurred so close together that a person had not healed from the first when the next one happened. ○ Age at first injury with LOC: Injuries with LOC occurring before 15 years of age are associated with greater cognitive and behavioral difficulties. There is some evidence that the earlier in life a TBI is experienced, the greater the effect on later behavior, especially self-control. ○ Severity of injury: More severe injuries are associated with greater cognitive and behavioral difficulties. Moderate and severe TBI's are certain to leave some permanent effects, even if the person recovered remarkably. Mild TBIs, especially those that cause more than momentary LOC may also have long-term effects. ○ Anoxic Injuries: Anoxic injuries are associated with cognitive and behavioral difficulties, especially problems with memory and concentration. <p>Psychometric Properties:</p>
<p>Rationale/Justification</p>	<p>Strengths:</p> <ul style="list-style-type: none"> ○ Assesses lifetime occurrence of multiple causes of TBI including accidents, sports injuries, and blast injuries ○ Well validated ○ TBI based on CDC definition <p>Weaknesses:</p> <ul style="list-style-type: none"> ○ Interviewer administered only. Not validated for self-administration. May want to use the risk factor questionnaire for head injury if self-administration is preferred. ○ Self-report of TBI history may under-report, however, this remains the gold standard.
<p>References</p>	<p>Key References:</p>

Corrigan JD, Bogner J. Screening and identification of TBI. J Head Trauma Rehabil. 2007 Nov-Dec;22(6):315-317.

Corrigan JD, Bogner J. Initial reliability and validity of the Ohio State University TBI Identification Method. J Head Trauma Rehabil. 2007 Nov-Dec;22(6):318-29.

Additional References:

Bogner J, Corrigan JD. Reliability and predictive validity of the Ohio State University TBI identification method with prisoners. J Head Trauma Rehabil. 2009 Jul-Aug;24(4):279-91.

Diamond PM, Harzke AJ, Magaletta PR, Cummins AG, Frankowski R. Screening for traumatic brain injury in an offender sample: a first look at the reliability and validity of the Traumatic Brain Injury Questionnaire. J Head Trauma Rehabil. 2007 Nov-Dec;22(6):330-8.

Gardner RC, Rivera E, O'Grady M, Doherty C, Yaffe K, Corrigan JD, Bogner J, Kramer J, Wilson F. Screening for Lifetime History of Traumatic Brain Injury Among Older American and Irish Adults at Risk for Dementia: Development and Validation of a Web-Based Survey. J Alzheimers Dis. 2020;74(2):699-711.

Hufstedler HC, Dorsman KA, Rivera EJ, Lanata SC, Bogner JA, Corrigan JD, Fuller SM, Borja XR, Wilson F, Gardner RC. Linguistic and Cultural Acceptability of a Spanish Translation of the Ohio State University Traumatic Brain Injury Identification Method Among Community-Dwelling Spanish-Dominant Older Adults. Arch Rehabil Res Clin Transl. 2019 Sep 6;1(3-4):100020.

Lequerica AH, Lucca C, Chiaravalloti ND, Ward I, Corrigan JD. Feasibility and Preliminary Validation of an Online Version of the Ohio State University Traumatic Brain Injury Identification Method. Arch Phys Med Rehabil. 2018 Sep;99(9):1811-1817.

National Center for Injury Prevention and Control (2003). Report to Congress on Mild Traumatic Brain Injury in the United States: Steps to Prevent a Serious Public Health Problem. Atlanta, GA, Centers for Disease Control and Prevention.

Setnik L, Bazarian JJ. The characteristics of patients who do not seek medical treatment for traumatic brain injury. Brain Inj. 2007 Jan;21(1):1-9.

Warner M, Barnes PM, Fingerhut LA; Centers for Disease Control and Prevention/National Center for Health Statistics. Injury and poisoning episodes and conditions: National Health Interview Survey, 1997. Vital Health Stat 10. 2000 Jul;(202):1-38.

Warner M, Schenker N, Heinen MA, Fingerhut LA. The effects of recall on reporting injury and poisoning episodes in the National Health Interview Survey. Inj Prev. 2005 Oct;11(5):282-7.

Document last updated ~~August 2022~~ December 2025

NINDS CDE Notice of Copyright Pediatric Glasgow Coma Scale (New for TBI)

Availability	Please visit this website for more information about the instrument: Pediatric Glasgow Coma Scale
Classification TBI v3.0 Classification Pending	
Short Description of Instrument	The Pediatric Glasgow Coma Scale (pGCS) score is a modified GCS score for use in infants and children. The pGCS uses age-appropriate modifications to account for developmental differences in verbal, motor, and cognitive abilities. Areas assessed are eye opening, verbal response, and motor response.
Comments/Special Instructions	If the participant is intubated, unconscious, or preverbal, the motor response is the most important aspect of the pGCS.
Scoring and Psychometric Properties	<p>Scoring: Score ≤ 12 represents a severe head injury. Score ≤ 8 represents the potential need for intubation and ventilation, as well as intracranial pressure monitoring.</p> <p>Psychometric Properties: Interobserver reliability is moderate to good for all components, with the grimace (motor response) score better than the verbal response score. Grimace (motor response) score may be useful in intubated patients when the verbal response score cannot be used (Tatman et al., 1997). The pediatric GCS performed has excellent inter-rater reliability, although reliability was reduced in patients with developmental disabilities and for intermediate range GCS responses (Kirschen et al., 2019).</p>
Rationale/Justification	<p>Strengths: The pGCS for children ≤ 2 years compares favorably with the standard GCS in evaluating blunt head trauma in children ≤ 2 years and accurately predicts the need for acute intervention (Holmes et al., 2005).</p> <p>Weaknesses: There is variation in application of GCS in pediatric patients.</p>
References	<p>Key References:</p> <p>James HE, Trauner DA (1985). The Glasgow Coma Scale. In: James HE, Anas NG, Perkin RM, editors. <i>Brain insults in infants and children: pathophysiology and management</i> (179–82). Orlando, Florida:Grune and Stratton Inc.</p> <p>Murray JP, Tyler DC, Jones TK, Stuntz JT, Lemire RJ. Coma scale for use in brain-injured children. Crit Care Med. 1984 Dec;12(12):1018-20.</p> <p>Additional References:</p> <p>Caruana M, Hackenbruch SN, Grech V, Farrugia R. Inconsistency in the Application of Glasgow Coma Scale in Pediatric Patients. Med Princ Pract. 2024;33(1):41-46.</p> <p>Kirkham FJ, Newton CR, Whitehouse W. Paediatric coma scales. Dev Med Child Neurol. 2008 Apr;50(4):267-74.</p> <p>Kirschen MP, Snyder M, Smith K, Lourie K, Agarwal K, DiDonato P, Doll A, Zhang B, Mensinger J, Ichord R, Shea JA, Berg RA, Nadkarni V, Topjian A. Inter-Rater Reliability Between Critical Care Nurses</p>

	<p>Performing a Pediatric Modification to the Glasgow Coma Scale. <i>Pediatr Crit Care Med</i>. 2019 Jul;20(7):660-666.</p> <p>Merck & Co, Inc. (2025). Modified Glasgow Coma Scale for Infants and Children. Retrieved 07Nov2025, from https://www.merckmanuals.com/professional/multimedia/table/modified-glasgow-coma-scale-for-infants-and-children.</p> <p>Tatman A, Warren A, Williams A, Powell JE, Whitehouse W. Development of a modified paediatric coma scale in intensive care clinical practice. <i>Arch Dis Child</i>. 1997 Dec;77(6):519-21.</p> <p>TBI-Specific References: Borgialli DA, Mahajan P, Hoyle JD Jr, Powell EC, Nadel FM, Tunik MG, Foerster A, Dong L, Miskin M, Dayan PS, Holmes JF, Kuppermann N; Pediatric Emergency Care Applied Research Network (PECARN). Performance of the Pediatric Glasgow Coma Scale Score in the Evaluation of Children With Blunt Head Trauma. <i>Acad Emerg Med</i>. 2016 Aug;23(8):878-84.</p> <p>Holmes JF, Palchak MJ, MacFarlane T, Kuppermann N. Performance of the pediatric glasgow coma scale in children with blunt head trauma. <i>Acad Emerg Med</i>. 2005 Sep;12(9):814-9.</p> <p><i>Document last updated November 2025</i></p>
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NINDS CDE Notice of Copyright Pediatric Risk of Mortality Score (New for TBI)

Availability	Please visit this website for more information about the instrument: Pediatric Risk of Mortality Score
Classification	Supplemental: Traumatic Brain Injury (TBI)
Short Description of Instrument	<p>The Pediatric Risk of Mortality (PRISM) score was developed from the Physiologic Stability Index (PSI).</p> <p>PRISM III was published in 1996. The score has 17 physiological variables divided into 26 ranges. The most predictive variables of mortality were minimum systolic blood pressure, abnormal pupillary reflexes, and stupor/coma (Pollack et al., 1996).</p> <p>PRISM IV was released in 2015. Physiological variables are measured only in the first 4 hours of Pediatric Intensive Care Unit (PICU) care. Laboratory variables are measured from 2 hours before PICU admission through the first 4 hours of PICU care (Pollack et al., 2013).</p>
Comments/Special Instructions	
Scoring and Psychometric Properties	<p>Scoring: PRISM is calculated using 14 routinely measured physiological variables and their ranges, such as blood pressure, heart rate, and laboratory values, during the first 12 hours of admission. The score is calculated by assigning a risk score for each variable based on its value and the patient's age. These individual scores are then combined and entered into a logistic function to produce the final PRISM score, which estimates the risk of mortality.</p> <p>Psychometric Properties: “The overall performance of the PRISM score-based predictive model was found to be good (goodness-of-fit test $\chi^2[5] = 5.49$; $p = .35$; area under receiver operating characteristic curve 0.92)” (Gemke et al., 1994). The PRISM has good discriminatory performance (area under the ROC curve was 0.851 (95% CI 0.790-0.912)) and good calibration (Hosmer and Lemeshow goodness-of-fit test; ($p = 0.627$, χ^2 square = 1.75, degree of freedom = 3)) (Taori et al., 2010).</p>
Rationale/Justification	<p>Strengths: The PRISM is a score used to quantify physiological status, which when combined with other variables, can measure expected mortality and morbidity risk. It provides an objective, evidence-based measure of a patient's sickness severity. The PRISM helps clinicians evaluate the severity of a child's condition and can be used for research and quality improvement initiatives.</p> <p>Weaknesses: The score is a population-based tool and should not be used to predict the outcome for an individual patient. Clinical judgment at the bedside is crucial.</p>
References	<p>Key References:</p> <p>Pollack MM, Ruttimann UE, Getson PR. Pediatric risk of mortality (PRISM) score. Crit Care Med. 1988 Nov;16(11):1110-6.</p> <p>Pollack MM, Holubkov R, Funai T, Dean JM, Berger JT, Wessel DL, Meert K, Berg RA, Newth CJ, Harrison RE, Carcillo J, Dalton H, Shanley T, Jenkins TL, Tamburro R; Eunice Kennedy Shriver</p>

National Institute of Child Health and Human Development Collaborative Pediatric Critical Care Research Network. The Pediatric Risk of Mortality Score: Update 2015. *Pediatr Crit Care Med*. 2016 Jan;17(1):2-9.

Pollack MM, Patel KM, Ruttimann UE. PRISM III: an updated Pediatric Risk of Mortality score. *Crit Care Med*. 1996 May;24(5):743-52

Additional References:

Collaborative Pediatric Critical Care Research Network. Pediatric Risk of Mortality (PRISM IV) Calculator. Retrieved 07N0v2025, from <https://www.cpccrn.org/calculators/prismivcalculator/>.

Gemke RJ, Bonsel GJ, van Vught AJ. Effectiveness and efficiency of a Dutch pediatric intensive care unit: validity and application of the Pediatric Risk of Mortality score. *Crit Care Med*. 1994 Sep;22(9):1477-84.

Taori RN, Lahiri KR, Tullu MS. Performance of PRISM (Pediatric Risk of Mortality) score and PIM (Pediatric Index of Mortality) score in a tertiary care pediatric ICU. *Indian J Pediatr*. 2010 Mar;77(3):267-71.

TBI-Specific References:

Document last updated December 2025

Baseline Risk Assessment

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Visit Date:
Visit Name:

1. **Age?
2. **Did participant experience hypoxic episode (oxygen saturation less than 90% for >5 min)?
(Choose one) ☐ Yes ☐ No ☐ Suspected ☐ Unknown
3. **Did participant experience hypotensive episode (~~see specific instructions for thresholds by age~~ ~~systolic BP <90 for longer than 5 minutes~~)? (Choose one)
☐ Yes ☐ No ☐ Suspected ☐ Unknown
4. Pupil reactivity assessment date and time:
5. How was pupil reactivity measured? (Choose one)
☐ Manually (if selected answer Questions 6 and 7)
☐ Using automated pupillometry (if selected answer Question 6-9)
6. *Left pupil reactivity: (Choose one)
☐ Sluggish
☐ Nonreactive
☐ Brisk
☐ Untestable
☐ Unknown
7. *Right pupil reactivity: (Choose one)
☐ Sluggish
☐ Nonreactive
☐ Brisk
☐ Untestable
☐ Unknown
8. Left pupil diameter (mm):
9. Right pupil diameter (mm):

~~*Subarachnoid hemorrhage~~
~~☐ Present ☐ Absent ☐ Indeterminate~~

~~**Marshall CT Code:~~
~~☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5~~
~~1-Diffuse injury, NVP: Intracranial pathology not visible on CT scan~~
~~2-Diffuse injury: Cisterns present with shift 0-5 mm, lesions present, but no high or mixed density lesion >25 cc. May include bone fragments and foreign bodies.~~
~~3-Diffuse injury with swelling: Cisterns compressed or absent, shift 0-5 mm, no high or mixed density lesion >25 cc~~
~~4-Diffuse injury with shift: Shift >5 mm, no high or mixed density lesion >25 cc.~~
~~5-Mass lesions: High or mixed density lesion > 25cc.~~

The Glasgow Coma Scale is classified as Disease Core and is strongly recommended for all TBI clinical studies. It should be completed whenever this CRF is completed. Additional information regarding the Glasgow Coma Scale and Pediatric Glasgow Coma Scale can be found here: [Link to be added once available.]

10. Glasgow Coma Scale assessment date and time:
11. Context of Glasgow Coma Scale assessment (Choose one):
☐ At injury scene
☐ At arrival in Emergency Department
☐ Post-resuscitation in Emergency Department
☐ At follow-up assessment

Baseline Risk Assessment

[Study Name/ID pre-filled]

Site Name:
Participant ID:

12. Are there confounders present that affect Glasgow Coma Scale assessment? (Choose all that apply)

- ☐ None
- ☐ Unknown
- ☐ Sedation/paralytics
- ☐ Intubation/tracheostomy
- ☐ Language barrier/aphasia
- ☐ Alcohol/drug intoxication
- ☐ Pre-existing neurologic deficits
- ☐ Severe facial trauma/edema
- ☐ Shock/hypothermia/metabolic derangements

~~Was participant sedated?~~

~~(Choose one) ☐ Yes ☐ No ☐ Unknown~~

Recorder Signature:

Date:

Baseline Risk Assessment CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements comprising a risk assessment for mortality or unfavorable outcome following traumatic brain injury expressed as fraction or percentage. It contains data elements that can be derived or pulled from other CRF modules and codified in a format to be entered into the prognostic model. The IMPACT prognostic model is used for moderate and severe TBI and the model proposed by CRASH trial is used for mild TBI. The CRF would be used in an initial assessment, but measurements should be repeated over time.

Important note: Some of the data elements are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies) or Supplemental – Highly Recommended (i.e., strongly recommended for all study designs and certain disease conditions or study types), as indicated by asterisks below.

*Element is classified as Disease Core

**Element is classified as Supplemental – Highly Recommended

The remaining data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study design and type(s).

The Supplemental CDEs are applicable to the following study designs: Clinical Trials, Observational Studies, Comparative Effectiveness Studies, and Epidemiologic Studies

The data elements on this CRF Module are part of the NINDS CDE Disease/Injury Related Events Domain.

Additional details regarding classification definitions are available: [Link to be added once available.]

Please see the Data Dictionary for element classifications.

~~Some of the data elements are classified as Core (i.e., strongly recommended for all TBI clinical studies to collect), or Basic (i.e., essential information for specified conditions, study types, or designs) as indicated by asterisks below.~~

~~*Element is classified as Core~~

~~Subarachnoid hemorrhage status~~

~~Glasgow Coma Scale (GCS) – Motor response scale~~

~~Pediatric Glasgow Coma Scale (PGCS) – Motor response score~~

~~**Element is classified as Basic for Acute Hospitalized studies:~~

~~Age value~~

~~Hypoxic episode indicator~~

~~Hypotensive episode indicator~~

~~Pupil reactivity light left eye result status~~

~~Pupil reactivity light right eye result status~~

~~Marshall CT classification code~~

~~**Element is classified as Basic for Concussion/Mild TBI studies:~~

~~Age value~~

~~**Element is classified as Basic for Moderate/Severe TBI: Rehabilitation studies:~~

~~Pupil reactivity light left eye result status~~

~~Pupil reactivity light right eye result status~~

Baseline Risk Assessment CRF Module Instructions

~~For other study types these CDEs are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study.~~

~~Sedation indicator is Supplemental for all study types.~~

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Age? – For children younger than one year born at less than 36 weeks gestation, it is recommended to also collect gestational age. Recording date of birth will give the most detailed information required for calculation of age and is recommended as first choice. However, in some studies recording date of birth may elicit discussions on a potential violation of privacy legislation and specifically HIPAA regulations. In these cases, the calculated age should be recorded.
- Did participant experience hypoxic episode (oxygen saturation less than 90% for >5 min)? – Choose one.
- Did participant experience hypotensive episode (~~systolic BP <90 for longer than 5 minutes~~)? – Choose one. This is an indicator of a hypotensive episode that is likely to result in neurological harm.
 - In adults, there is increasing evidence that the past hypotension threshold of a systolic blood pressure (SBP) of 90 mmHg is too low. Several recent studies have suggested that SBP levels lower than 110-130 mmHg may be associated with worse outcomes. Given the evolving knowledge in this area, and recognizing that the TQIP TBI Guidelines (<https://www.facs.org/media/vgfgjpfk/best-practices-guidelines-traumatic-brain-injury.pdf>) recommend maintaining a SBP > 110 mmHg, this CRF defines a hypotensive episode in adults as a SBP < 110 mmHg.
 - In children, a hypotensive episode is defined (<https://doi.org/10.1080/10903127.2023.2187905>) as systolic blood pressure < 75th-90th percentile of normal for age. Systolic blood pressure targets are as follows:
 - 28 days and younger >70 mmHg
 - 1–12 months > 84 mmHg
 - 1–5 years > 90 mmHg
 - 6 years and older > 100 mmHg
- Pupil reactivity assessment date and time – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- How was pupil reactivity measured? – Choose one.
- Left pupil reactivity – Choose one. Ideally, pupillometry should be conducted in dim light for reactivity to be detected.
- Right pupil reactivity – Choose one. Ideally, pupillometry should be conducted in dim light for reactivity to be detected.
- ~~Subarachnoid hemorrhage status – Choose one.~~
- ~~Marshall CT classification code – Choose one.~~
- Left pupil diameter (mm) – Record left pupil diameter in millimeters (mm). Ideally, pupillometry should be conducted in dim light for reactivity to be detected. If using automated pupillometry, record the maximum pupil diameter before light is shown.
- Right pupil diameter (mm) – Record right pupil diameter in millimeters (mm). Ideally, pupillometry should be conducted in dim light for reactivity to be detected. If using automated pupillometry, record the maximum pupil diameter before light is shown.
- Glasgow Coma Scale assessment date and time – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are

Baseline Risk Assessment CRF Module Instructions

prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.

- Context of Glasgow Coma Scale assessment – Choose one.
- Are there confounders present that affect Glasgow Coma Scale assessment (Choose all that apply)? – Choose all that apply.
- ~~Sedation indicator – Choose one.~~

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Baseline Risk Assessment CRF Module Instructions

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Blast Exposure

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Visit Date:
Visit Name:

1. Test Series Information (including one or more Test Shots)

- a. Test Series Number:
- b. Test Series Date and Time:
- c. ******Charge Descriptions:
- d. ******Test Description:
- e. Distribution Code (OPSEC Determined): ☐ A ☐ B ☐ C ☐ D ☐ E ☐ F
- f. Air Temperature: units
- g. Air Pressure: units
- h. Cross Wind Magnitude and Direction:
- i. Pressure Source Description:
- j. Test Review Documentation: ☐ Available ☐ Not Available
- k. Companion Security Release Form: ☐ Required ☐ Not Required
- l. Test After Report: ☐ Available ☐ Not Available
- m. ******Test Setup Diagrams:
- n. Document Name:
- o. Document Category: ☐ Image ☐ Test Report ☐ Pre-Test Review
- p. Document Description:
- q. Tags:

- | | |
|--|--|
| <input type="checkbox"/> Home Made Explosive | <input type="checkbox"/> 60mm Mortar Muzzle Shock |
| <input type="checkbox"/> Conventional Explosive | <input type="checkbox"/> 120mm Tank Muzzle Shock |
| <input type="checkbox"/> Metallized Explosive | <input type="checkbox"/> Shoulder Fired Rocket Air Shock |
| <input type="checkbox"/> Interior | <input type="checkbox"/> Behind Armor Air Shock |
| <input type="checkbox"/> Exterior | <input type="checkbox"/> Near Field |
| <input type="checkbox"/> Buried Explosive | <input type="checkbox"/> Medium Field |
| <input type="checkbox"/> Air Burst | <input type="checkbox"/> Far Field |
| <input type="checkbox"/> 155mm Muzzle Shock | <input type="checkbox"/> Ground Shock |
| <input type="checkbox"/> 120mm Mortar Muzzle Shock | <input type="checkbox"/> Other, specify: |
| <input type="checkbox"/> 81mm Mortar Muzzle Shock | |

2. Test Shot (within Test Series)

- a. Individual Test Shot Number:
- b. Test Shot Distribution Level: ☐ A ☐ B ☐ C ☐ D ☐ E ☐ F
- c. Test Shot Designated FOUO Level: ☐ UNCLAS ☐ FOUO ☐ NOFORN ☐ SECRET
- d. Date **and** Time:
- e. Gauge #:
- f. ******Line of Sight Distance of Gauge to the Target:
- g. Pressure Data: ☐ Yes ☐ No
- h. Acceleration Data: ☐ Yes ☐ No
- i. Pressure Tabular Input:
- j. Acceleration Tabular Input:
- k. Air Temperature:
- l. Cross Wind Magnitude and Direction:
- m. Pressure Source
 - i. Gun/explosive Type:
 - ii. Orientation:
 - iii. Charge Weight:
 - iv. Charge Shape:

Blast Exposure

[Study Name/ID pre-filled]

Site Name:
Participant ID:

- n. Target Description:
- o. # of Gauges Per Shot:
- p. Pre and Post Shot Images: ☐ Not Available ☐ Available, Format:
- q. Shot Notes:

3. Gauge Information

- a. Gauge Manufacturer/Model/Number:
- b. Material/Personnel:
- c. Height Above Ground:
- d. Gauge Orientation Angled from North (approximate):
- e. Gauge Orientation Angled from Horizontal (approximate):
- f. Personnel Stance:
- g. ******Location on Personnel:
- h. ******Pressure Time History:
- i. Pressure Sampling Rate:
- j. Acceleration Time History (G's vs. time):
- k. Acceleration Sampling Rate:

4. Summary Data

- a. Per Shot Peak PSI:
- b. Per Shot Impulse:
- c. Per Shot Duration (positive phase):
- d. Per Shot Number of Peaks:
- e. Per Shot Use of Multiple Sensors? ☐ No ☐ Yes, Number of Units:
- f. Per Series Number of Exposure Events:

5. Outcome Measures

- a. Source/type of Information:

6. Other Information

- a. Helmet Type:
- b. Other PPE:

Recorder Signature:

Date:

Blast Exposure CRF Module Instructions

GENERAL INSTRUCTIONS

The technology and work to date has leveraged blast overpressure so that has shaped the development of these CDE recommendations. There are alternate methods of recording blast exposure (e.g., optical, acoustic) that have not been used with any regularity in the relevant line of research and are not suitable to use as a source for shaping CDEs at the present time, but should be accommodated in a consolidation of evidence.

Important note: None of the data elements included on this CRF Module are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies).

~~Some of the data elements are classified as Supplemental Highly Recommended (i.e., strongly recommended for Biomechanical Devices in TBI clinical studies to collect).~~

~~**Element is classified as Supplemental—Highly Recommended:~~

~~Charge Description~~

~~Test Description~~

~~Test Setup Diagrams (including orientation)~~

~~Line of Sight Distance of Gauge to the Target~~

~~Gauge Location on Personnel~~

~~Gauge Pressure Time History~~

All the data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study design and type(s).

The Supplemental CDEs are applicable to the following study designs and types: Clinical Trials, Observational Studies, and Epidemiologic Studies of human occupational blast exposure on an appropriate firing or blast range following existing range safety guidelines.

The data elements on this CRF Module are part of the NINDS CDE Disease/Injury Related Events Domain.

Additional details regarding classification definitions are available:[Link to be added once available.]

Please see the Data Dictionary for element classifications.

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Test Series Number – End state is a series numbering system that is centralized and spans across all labs doing relevant work, assigned prior to the conduct of each test series. However, there is not a sufficient mechanisms for that centralization of series numbering at present, so the recommended Test Series identifier is [PI or LAB text identifier] followed by a serial number for work conducted by that lab.
- Test Series Date and Time – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- Charge Descriptions – Single line free field text
- Test Description – Single line free field text
- Distribution Code (OPSEC Determined) – A, B, C, D, E, F [reference <https://www.dodcui.mil/Distribution-Statements/>]
- Air Temperature – Degrees Celsius measured at beginning of Test Series (measured method not constrained).

Blast Exposure CRF Module Instructions

- Air Pressure – Any standardized measure at beginning of Test Series (measurement method not constrained)
- Cross Wind Magnitude – Any standardized measure at beginning of Test Series (measurement method not constrained)
- Cross Wind Direction – Any standardized measure at beginning of Test Series; Direction is direction of flow angled from North (approximate) (measurement method not constrained)
- Pressure Source Description – Single line free field text
- Test Review Documentation – Available/Not Available
- Companion Security Release Form – Required/Not Required
- Test After Report – Available/Not Available
- Test Setup Diagrams – Diagram/Image/Topological Map of Area/Lidar XYZ Scan of Area and Format (jpg, bmp, pdf, etc)
- Document Name – Single line free text
- Document Category – Image/Test Report/Pre-Test Review
- Document Description – Single line free text
- Individual Test Shot Number – Serial number within Test Series
- Test Shot Distribution Level – A, B, C, D, E, F
- Gauge # – Serial number(s) of blast gauges that are used
- Line of Sight Distance of Gauge to the Target – Any standardized measure (measurement method not constrained)
- Pressure Tabular Input – Two columns, (Time/Pressure)
- Acceleration Tabular Input – Two columns, (Time/Acceleration (G's))
- Air Temperature – Degrees Celsius measured at beginning of Test Shot (measurement method not constrained)
- Cross Wind Magnitude and Direction – Any standardized measure at beginning of Test Series; Direction is direction of flow angled from North (approximate) (measurement method not constrained)
- Target Description – Single line free field text
- # of Gauges Per Shot – Integer
- Pre and Post Shot Images – Not Available/Available (and format of image)
- Shot Notes – Multiple line free field text
- Gauge Manufacturer/Model/Number – Free field text
- Material/Personnel – Type of subject, if any (free field text)
- Height Above Ground – Any standardized measure (measurement method not constrained)
- Gauge Orientation Angled from North (approximate) – Angle from North (approximate) (measurement method not constrained)
- Personnel Stance – Free field text entry
- Location on Personnel – Free field text entry, location of blast gauges on personnel's body
- Pressure Time History – Two columns, (Time/Pressure)
- Pressure Sampling Rate – Standardized pressure measurement vs. time, free field text entry
- Acceleration Time History (G's vs. time) – Two columns, (Time/Acceleration (G's))
- Acceleration Sampling Rate – Standardized acceleration measurement vs. time, free field text entry
- Per Shot Peak PSI – Real number in PSI
- Per Shot Impulse – Pounds per square inch times milliseconds, or psi-ms
- Per Shot Duration (positive phase) – Time duration of overpressure greater than pre-shot baseline
- Per Shot Number of Peaks – Integer, number of times during overpressure positive phase when pressure time history shows continuous increase across time.
- Per Shot Use of Multiple Sensors? – No/Yes; Integer for Number of Units
- Per Series Number of Exposure Events – Integer
- Source/Type of Information – Free text entry
- Helmet Type – Free text entry
- Other PPE – Free text entry

Blast Exposure CRF Module Instructions

For items labeled as ‘measurement not constrained’ the goal is to ease the burden of data transformation at data entry. Instead, the burden of transforming data to other scales (if warranted) would be accommodated by the storage host or by the user of any data.

REFERENCES

Head Kinematics Estimates

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Visit Date:
Visit Name:

SUBJECT PARTICIPANT INFORMATION

Subject age: years, months

Subject gender: ☐ Female ☐ Male ☐ Unknown ☐ Unspecified ☐ Not reported

Subject height: ☐ Feet ☐ Meters ☐ Inches ☐ Centimeters

Subject weight: ☐ lbs ☐ kgs

Subject head size (circumference): ☐ Inches ☐ Centimeters

Participant age, sex at birth, height, weight, and head circumference should be collected whenever Head Kinematics data are collected, see the Demographics CRF and Height and Weight CRF.

1. Sport (see instructions):
2. Position (see instructions):
3. **Subject Participant's** competition level: ☐ Rec ☐ Club ☐ Scholastic below HS ☐ HS ☐ College ☐ Professional ☐ Military ☐ Other

ACTIVITY

4. Activity at time of event: ☐ Warm-up (if discernible) ☐ Practice ☐ Game ☐ Scrimmage ☐ Laboratory event

DATA COLLECTION

5. Start of data collection (date / time)
 - a. Date of first event:
 - b. Time of first event: ☐ am ☐ pm ☐ 24-hour clock
6. End of data collection (date / time)
 - a. Date of last event:
 - b. Time of last event: ☐ am ☐ pm ☐ 24-hour clock
7. Number of Exposures (Also see Video Device Confirmation CRF)
 - a. ******Total number of exposures registered:
 - b. True positive exposures are confirmed in video: ☐ Yes ☐ No
 - c. If answer to 'b' is Yes, include description of video confirmation method or citation and complete Video Device Confirmation CRF
 - d. Exposures are confirmed with **published** detection algorithm: ☐ Yes ☐ No (See Video Device Confirmation CRF)
 - e. If answer to 'd' is Yes, include description of detection method and validation performance or citation:

SENSOR AND HELMET INFORMATION

8. Sensor and Helmet
 - a. *******Device: ☐ Single ☐ Multiple
 - b. ******Sensor types (Choose all that apply):

<input type="checkbox"/> Linear accelerometer	<input type="checkbox"/> Force
<input type="checkbox"/> Gyroscope	<input type="checkbox"/> Pressure
<input type="checkbox"/> Angular accelerometer	<input type="checkbox"/> Other, specify:
 - c. ******Sensor manufacturer/vendor:
 - d. ******Sensor model (if any):
 - e. Helmet manufacturer (if any):
 - f. Helmet model (if any):

Head Kinematics Estimates

[Study Name/ID pre-filled]

Site Name:
Participant ID:

g. Helmet size (if any):

- ☐ 2XS
- ☐ XS
- ☐ S
- ☐ M
- ☐ L
- ☐ XL
- ☐ 2XL
- ☐ 3XL

- ☐ 4XL
- ☐ 5XL
- ☐ Youth S
- ☐ Youth M
- ☐ Youth L
- ☐ Youth S/M
- ☐ Youth L/XL
- ☐ Other, specify:

~~Device mounting location [or interface and location]:~~

- ☐ ~~Helmet~~
- ☐ ~~Mouth guard~~
- ☐ ~~Left ear~~
- ☐ ~~Right ear~~

- ☐ ~~Skin~~
- ☐ ~~Teeth~~
- ☐ ~~Ear canal~~
- ☐ ~~Other, specify:~~

~~For mouth guard: ☐ Custom ☐ Boil-and-bite model~~

h. **Hardware version:

i. **Sensor firmware version:

j. **Software version:

k. **Device type:

- ☐ Ear piece
- ☐ Helmet liner
- ☐ Custom mouth ~~guard piece~~
~~(thermoformed, 3D printed)~~
- ☐ Boil-and-bite mouth ~~guard piece~~
~~(injection molded, 3D printed)~~

- ☐ Retainer
- ☐ Skin patch
- ☐ Headband
- ☐ Other, specify:

l. **Anatomical location of sensing device on user's head:

- ☐ Ear canal
- ☐ Maxilla
- ☐ Mandible
- ☐ ~~Upper jaw/Teeth~~
- ☐ Parietal

- ☐ Frontal
- ☐ Temporal
- ☐ Occiput
- ☐ Palate

m. **Impact duration/sampling window:

- i. Pre-trigger: (ms)
- ii. Post-trigger: (ms)
- iii. Total record length: (ms)

~~***Laboratory ranges of kinematic calibration for instrument (e.g., bare head between 20g to 100g; American football between 25g to 100g to forehead, front boss, side, rear):~~

~~OR Indicate: ☐ Custom calibration ☐ Standard sensor star rating~~

n. **Data storage (trigger) threshold:

9. Linear Accelerometer Sensor Information (information may be available from manufacturer part number)

a. **Linear acceleration unit: ☐ g ☐ m/s²

b. **Accelerometer full scale range, +/- (m/sec²):

c. **Accelerometer sampling rate (Hz):

~~Exploratory Data Elements:~~

~~***Accelerometer nominal non-linearity, (% of output):~~

~~***Accelerometer calibration type and calibration constants: ☐ None ☐ Linear $Y=mX+B$ ☐ Non-linear $Y=kX^n$~~

~~***Accelerometer 0dB pass-band, (f1 f2, Hz):~~

d. Accelerometer analog pre-filter type: ☐ None ☐ 4th Order Butterworth ☐ Dynamic, specify: ☐ Other, specify:

e. Accelerometer analog pre-filter -3dB corner frequency, (Hz):

Head Kinematics Estimates

[Study Name/ID pre-filled]

Site Name:
Participant ID:

- f. Are angular accelerations derived from linear accelerometer outputs? ☐ Yes ☐ No
i. Derivation method:
g. Angular accelerations are confirmed with published method: ☐ Yes ☐ No
h. If answer to 'g' is Yes, include citation, if not include description:

10. Angular Sensor Information (information may be available from manufacturer part number)
a. ****Does sensor directly measure** ☐ angular velocity in rad/sec or ☐ angular acceleration in rad/s²?
b. ~~Gyroscope Angular sensor~~ full scale range, +/- ~~(rad/s)~~:
c. ~~Gyroscope Angular sensor~~ sampling rate, (Hz):

~~Exploratory Data Elements:~~

~~***Gyroscope Angular sensor calibration type and constants ☐ None ☐ Linear form $Y=mX+B$ ☐ Non-linear form $Y=kX^n$~~

~~***Angular sensor Gyroscope nominal non-linearity, (% of output):~~

~~***Angular sensor Gyroscope 0dB pass-band, (f1-f2, Hz):~~

- d. Analog pre-filter type: ☐ None ☐ 4th Order Butterworth ☐ Brick Wall ☐ **Dynamic, specify:** ☐ Other, specify:
e. **Angular sensor Gyroscope** filter -3dB corner frequency, (Hz):
f. If angular velocity sensor, are angular accelerations derivatives? ☐ Yes ☐ No
i. Derivation method:
g. If gyroscope, what equation was used to compute derivative?
h. ****If No**, indicate coordinate definition for transformation purposes:

11. ****Are the data filtered based on standards according to SAE J211?** ☐ Yes ☐ No
a. ****If No**, additional filter specifications should be given:
b. ****Specify filter type:**

SENSOR DATA COLLECTION

12. Head Linear Acceleration Information

~~***Estimated frequency content of linear acceleration pulse, to compare against sensor optimal ranges of performance (Hz):~~

- a. ****Peak linear acceleration x:** ☐ g ☐ m/s²
b. ****Peak linear acceleration y:** ☐ g ☐ m/s²
c. ****Peak linear acceleration z:** ☐ g ☐ m/s²
d. Scalar of linear acceleration (RSS value):

13. ~~***~~Linear velocity:

14. Head Angular Velocity Information

~~**Estimated frequency content of angular velocity pulse (Hz — if different than linear acceleration):~~

- a. ****Peak change in rotational-angular velocity x:** ☐ rad/s ☐ deg/s
b. ****Peak change in rotational-angular velocity y:** ☐ rad/s ☐ deg/s
c. ****Peak change in rotational-angular velocity z:** ☐ rad/s ☐ deg/s
d. ****Peak change in rotational-angular velocity:** ☐ scalar ☐ rad/s ☐ deg/s

15. Head Angular Acceleration Information

~~**Estimated frequency content of angular (rotational) acceleration pulse (Hz — if different than linear acceleration):~~

- a. ****Peak rotational-angular acceleration x:** ☐ rad/s² ☐ deg/s²
b. ****Peak rotational-angular acceleration y:** ☐ rad/s² ☐ deg/s²
c. ****Peak rotational-angular acceleration z:** ☐ rad/s² ☐ deg/s²
d. ****Peak rotational-angular acceleration magnitude:** ☐ scalar ☐ rad/s² ☐ deg/s²

Head Kinematics Estimates

[Study Name/ID pre-filled]

Site Name:
Participant ID:

~~The following are Exploratory Data Elements that may be considered:~~

16. Head Kinematic Injury Criteria

- a. ****Head Injury Criterion (HIC):** ☐ Not calculated
 - i. Specify: ☐ HIC15 ☐ HIC36
- b. ****Severity Index (SI):** ☐ Not calculated
- c. ****Brain Injury Criterion (BrIC):** ☐ Not calculated
- d. ****Rotational Injury Criterion (RIC):** ☐ Not calculated
- e. ****Power Rotational Head Injury Criterion (PRHIC):** ☐ Not calculated
- f. ****Head Impact Power (HIP):** ☐ Not calculated
- g. ****HIT Severity Profile (HITsp):** ☐ Not calculated
- h. ****Diffuse Axonal Multi-Axis General Evaluation (DAMAGE):** ☐ Not calculated
- i. ****Head Acceleration Response Metric (HARM):** ☐ Not calculated

17. ****Peak principal strain:** ☐ Not calculated

18. ****Peak fiber oriented strain:** ☐ Not calculated

19. ****FE Model Name:** ☐ ABM ☐ GHBMCM ☐ THUMS ☐ WHIM ☐ Other, specify: ☐ Not calculated

20. ****FE Model Version:** ☐ Not calculated

21. Impact location/~~direction~~ on the head: ☐ Top ☐ Rear ☐ Side ☐ Front ☐ Other, specify:

22. Impact source: ☐ Head to body ☐ Head to ground ☐ Head to head ☐ Other, specify:

Recorder Signature:

TBI CDEs Version 2.1

Date

Initials:

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Head Kinematics Estimates CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements that relate to the collection of head kinematics via sensors during sporting events – both in live play (practice or games) or in laboratory settings.

Important note: None of the data elements included on this CRF Module are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies). Some of the data elements are classified as Supplemental – Highly Recommended (i.e., strongly recommended for all study designs and certain disease conditions or study types), as indicated by asterisks below, and should be collected if biomechanical device studies are performed.

****Element is classified as Supplemental – Highly Recommended**

The remaining data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study design and type(s).

The Supplemental CDEs are applicable to the following study designs: Clinical Trials, Observational Studies, Comparative Effectiveness Studies, and Epidemiologic Studies

The data elements on this CRF Module are part of the NINDS CDE Disease/Injury Related Events Domain.

Additional details regarding classification definitions are available: [Link to be added once available.]

Please see the Data Dictionary for element classifications.

~~Most data elements on this form are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study. However, the data elements noted with two asterisks (**) on this CRF Module are classified as Supplemental – Highly Recommended (i.e., strongly recommended for Biomechanical Devices in TBI clinical studies to collect). In addition, the data elements noted with three asterisks (***) on this CRF Module are classified as Exploratory (i.e., reasonable to use for Biomechanical Devices in TBI clinical studies since they fill in a needed gap but need further validation).~~

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- ~~• Subject age – No further instructions~~
- ~~• Subject gender – No further instructions~~
- ~~• Subject height – No further instructions~~
- ~~• Subject weight – No further instructions~~
- ~~• Subject head size (circumference) – Head circumference should be measured with a non-stretch tape held firmly, but without squeezing the skin, in the horizontal plane through the glabella [forehead above eyebrows] and opisthocranium [posterior most point of the occiput].
https://www.ejmanager.com/mnstemps/134/1997_4_3_1.pdf~~
- Sport (See Table 2 for list) – Select from list of permissible values below. Note: This information may make the data personal identifiable along with position.
- Position (See Table 2 for list) – The primary position of the participant at the time of the event(s). Select from list of permissible values for each sport. Note: Depending on the sample size, this data may be personally identifiable. It is up to the researcher to determine if this information should be collected.
- **Subject-Participant's** competition level – Competition level of practice or game participated in ~~by subject~~ at time of recording of exposure event. Determine competition level based on official practice or competition category. If other, ~~or laboratory/ exploratory, etc.~~, record if so. Note: Recreation ('Rec') is non-competitive recreational sport while competitive recreational is referred to as 'Club'.

Head Kinematics Estimates CRF Module Instructions

- Activity at time of event – Select from the options provided. 'Warm-up' may not be discernible and may not be included in the options.
- Start of data collection – The date/time when data acquisition started. Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- Date of first ~~recorded~~ event and Time of first ~~recorded~~ event – Report the time and date when the first event was recorded. Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- End of data collection - The date/time when data acquisition ended. Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- Date of last ~~recorded~~ event and Time of last ~~recorded~~ event – Report the time and date when the last event was recorded. Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- Number of Exposures
 - Total number of exposures registered – A single exposure refers to one occurrence of head impact/inertial exposure. The number of exposures registered refers to the total number of such occurrences over the duration of data collection (start and end times defined by CDEs 2 and 3). For example, if data collection occurred over a single American Football game for one player, and the player's head accelerometry device registered 30 impacts, the number of exposures registered would be 30. It is important to consider that for some sensor systems that don't differentiate between actual play and things like halftime or water breaks, it can be challenging to differentiate true head impacts from jumping up or down for example, unless that is the question being asked.
 - If any of the answers to 'b' or 'd' is Yes, please enter the number of exposures after confirming with video or detection algorithm.
 - True positive exposures are confirmed in video – State whether the exposures indicated in a have been confirmed in video recordings of the activity. For example, if registered head impacts from an American Football game were observed in game video to occur at the times indicated by the data recordings, the answer would be Yes. Select Yes or No.
 - If answer to 'b' is Yes, include description of video confirmation method or citation. Include a text description of the method used, or a citation of the method, including whether all exposures have been video confirmed or a partial subset.
 - Impacts are confirmed with validated impact detection algorithm – State whether the exposures indicated in a have been confirmed or detected by a validated method to detect exposure. For example, if registered head impacts from an American Football game were confirmed by a validated head impact detection algorithm to be head impacts (instead of spurious recordings), then the answer would be Yes. Select Yes or No.
 - If answer to 'd' is Yes, include description of impact detection method or citation – Include a text description of the method used and validation performance, or a citation of the method.
- Sensor and Helmet Information – Information regarding sensor device type and performance specifications, and helmet type (if applicable) and specifications. Fill out required items a-n.

Head Kinematics Estimates CRF Module Instructions

- Device – Single or multiple devices (not sensors) used for data collection. If multiple devices are used, will require entry for each device. Check appropriate box. If multiple devices are employed, information will be required for each device.
- Sensor type(s) – Choose all that apply: Linear accelerometer, Gyroscope, Angular accelerometer, Force, Pressure, Other, specify (any other type of sensor, specify). Fill in the appropriate sensor type per the definition.
- Sensor manufacturer/vendor – Vendor of the sensor or if vendor and manufacturer are identical then the manufacturer of the final assembled sensor package. Fill in the appropriate vendor per the instructions.
- Sensor model (if any) – Model name and number for final assembled sensor package if available. Fill in the appropriate vendor per the instructions.
- Helmet manufacturer (if any) – Helmet manufacturer (company) owning the design and marketing the helmet. Fill in the appropriate helmet manufacturer per the instructions.
- Helmet model (if any) – Helmet model number for helmet per vendor or manufacturer.
- Helmet size (if any) – Per most common available sizes, 2 extra small to 5 extra-large, and youth small to youth large/extra-large. 2 extra small, extra small, small, medium, large, extra-large, 2 extra-large, 3 extra-large, 4 extra-large, 5 extra-large, youth small, youth medium, youth large, youth small/medium, youth large/extra-large. If another numeric size convention is used, then provide the number and units or convention in other (specify). Fill in the appropriate helmet size per the instructions, or fill in the other numeric convention and units or convention name in other (specify).
- ~~○ Device mounting location (or interface and location) – Location of placement of final assembled device, including helmet (inside helmet), mouthguard, ear (left or right), skin, teeth, ear canal, or other (specify). Fill in the appropriate device mounting location or interface and location per the instructions.~~
- Hardware version – Per vendor - hardware number for final assembled device for vendor sensor hardware and date of manufacture if available. Fill in the appropriate hardware version per the definition.
- Sensor firmware version – Per vendor - firmware hardware version number and date of firmware if available. Fill in the appropriate firmware version per the definition.
- Software version - Per vendor - sometimes postprocessing of data is performed in software and if so, record pc or app software version and platform, Windows 10, OSX High Sierra, etc. Fill in the appropriate software version per the definition.
- Device type - Ear piece, Helmet liner, Custom mouth-guard (thermoformed, 3D-printed) piece, Boil-and-bite mouth-guard (injection molded, 3D-printed) piece, Retainer, Skin patch, Headband, Other, specify. Record the general device type as advertised and under intended use.
- Anatomical location of sensing device on user's head – Location the device is mounted for data collection; general locations are anatomic locations on the head.
- Impact Exposure duration/sampling window – Length of time data is collected for a given exposure. Record time in milliseconds, both pre-trigger, post-trigger, or pre- and post-trigger total (milliseconds).
- Data storage threshold – This is the trigger threshold used to trigger an impact. Specified as linear acceleration, angular acceleration, angular velocity or a combination (check all that apply). Also, if the algorithm requires the signal to exceed a given threshold for a minimum amount of time that should be included as 'MTOM, minimum time over threshold, samples or ms for units'. Specify if triggering is possible independently by axis and enter each if so. Check proprietary option and provide practical threshold in practice as well. Fill trigger threshold.
- Linear Accelerometer Sensor Information – No further instructions.
- Angular Sensor Information – No further instructions.
- Are the data filtered based on standards according to SAE J211? – ~~No further instructions. The current data standard should be used~~ (e.g., Under future consideration: Use of SAE J1734.)
- Data filter type – http://standards.sae.org/j211/1_201403/

Head Kinematics Estimates CRF Module Instructions

- Head Linear Acceleration Information—~~No further instructions~~
 - ~~Scalar of linear acceleration – Residual sum of squares (RSS) value.~~
- Head Angular Velocity Information—~~No further instructions~~
 - ~~Peak change in angular velocity – Radians or Degrees.~~
- Head Angular Acceleration Information—~~No further instructions~~
 - ~~Head impact peak angular acceleration magnitude value – Radians or Degrees.~~
- Head Kinematic Injury Criteria (Table 1)

Table 1

Criterion	Value	Definition	Reference/Notes
Head Injury Criterion (HIC)	Numeric value, >0	Linear acceleration using “g” as unit, time “ms” as unit. See REF for equation.	Versace, J., "A Review of the Severity Index," SAE Technical Paper 710881, 1971, https://doi.org/10.4271/710881 .
			Specify HIC15 or HIC36
Severity Index (SI)	Numeric value, >0	It was formulated by fitting the Wayne State Tolerance Curve, which is based on skull fracture data. It incorporates impact duration into the assessment of head and brain injury risk. Linear acceleration using “g” as unit, time “ms” as unit. See Ref for equation.	Gadd, C., "Use of a Weighted-Impulse Criterion for Estimating Injury Hazard," SAE Technical Paper 660793, 1966, https://doi.org/10.4271/660793 .
			The integral is evaluated over the period of time from when the linear acceleration first exceeds 4g to when it returns to 4g after the largest peak.
Brain Injury Criterion (BrIC)	Numeric value, >0	Formulated using the maximum magnitudes of	Takhounts, E., Craig, M., Moorhouse, K., McFadden, J., Hasija, V., "Development of Brain Injury Criteria (BrIC)," SAE Technical Paper 2013-22-0010, 2013, https://doi.org/10.4271/2013-22-0010 .

Head Kinematics Estimates CRF Module Instructions

Criterion	Value	Definition	Reference/Notes
		the three orthogonal head angular velocity components.	Takhounts EG, Craig MJ, Moorhouse K, McFadden J, Hasija V. Development of brain injury criteria (BrIC). Stapp Car Crash J. 2013 Nov;57:243-66.
			Critical velocity values are model-dependent, and also rely on an injury dataset to produce the 50% injury probability.
Rotational Injury Criterion (RIC)	Numeric value, >0	This is a HIC analogue by replacing linear acceleration with rotational angular acceleration.	Kimpara H, Iwamoto M. Mild traumatic brain injury predictors based on angular accelerations during impacts. Ann Biomed Eng. 2012 Jan;40(1):114-26.
			Time interval bound to 36 ms.
Power Rotational Head Injury Criterion (PRHIC)	Numeric value, >0	See Ref for equation.	Kimpara H, Nakahira Y, Iwamoto M, Rowson S, Duma SM. Head Injury Prediction Methods Based on 6 Degree of Freedom Head Acceleration Measurements during Impact. Int. J. Automot. Engineering 2011;2:13-9. https://www.jstage.jst.go.jp/article/jsaeijae/2/2/2_20114490/_pdf/-char/en
Head Impact Power (HIP)	Numeric value, >0	See Ref for equation.	Newman JA, Shewchenko N, Welbourne E. A proposed new biomechanical head injury assessment function - the maximum power index. Stapp Car Crash J. 2000 Nov;44:215-47.
			The maximum is taken over the entire 100 ms window when sensor measurements are recorded.
HIT Severity Profile (HITsp)	Numeric value, >0	A weighted sum of peak linear and rotational angular accelerations, HIC, and Gadd SI with empirically determined weights. See Ref for equation.	Greenwald RM, Gwin JT, Chu JJ, Crisco JJ. Head impact severity measures for evaluating mild traumatic brain injury risk exposure. Neurosurgery. 2008 Apr;62(4):789-98; discussion 798.
			HITsp is effectively a commercial name of Principal Component Score (PCS). They are identical.

Head Kinematics Estimates CRF Module Instructions

Criterion	Value	Definition	Reference/Notes
Diffuse Axonal Multi-Axis General Evaluation (DAMAGE)	Numeric value, >0	An equation representing a second-order mechanical system that uses directionally dependent angular acceleration time histories.	Gabler LF, Crandall JR, Panzer MB. Development of a Second-Order System for Rapid Estimation of Maximum Brain Strain. Ann Biomed Eng. 2019 Sep;47(9):1971-1981.
Head Acceleration Response Metric (HARM)	Numeric value, >0	A linear combination of HIC and DAMAGE	Bailey AM, Sanchez EJ, Park G, Gabler LF, Funk JR, Crandall JR, Wonnacott M, Withnall C, Myers BS, Arbogast KB. Development and Evaluation of a Test Method for Assessing the Performance of American Football Helmets. Ann Biomed Eng. 2020 Nov;48(11):2566-2579.

- Peak principal strain – Recommend 95th percentile peak maximum principal strain value among all elements in the brain mesh. If possible, also recommend reporting where this peak value occurred in the brain.
- Peak fiber oriented strain – Recommend 95th percentile peak strain value along the white matter fiber direction within the brain. Also recommend to specify the technique used to report the fiber-oriented strain, e.g., sampled from FE elements or from neuroimaging. If possible, also recommend reporting where this peak value occurred in the brain white matter region, based on an atlas.
- FE Model Name – Abbreviation of the head injury model name used; e.g., ABM, GHBM, THUMS, WHIM, etc.
- FE Model Version – Currently, it is not typical to report a model version number except for a few (GHBM/THUMS). Recommend to report a major and a minor version number in the future, e.g., Version 1.0, Version 2.1. Also recommend providing citation of the model description and validation for the specific model. Need to further discuss what constitutes a major version vs. a minor version – for example, change of head/brain meshing, change of material property (isotropic vs. anisotropic), etc. may constitute a major version, while geometrical scaling and revision on brain-skull boundary conditions, etc. may be a minor version.
- Impact location on the head - Choose one.
- Impact source - Choose one.

REFERENCES

Bartsch A, Samorezov S. Cleveland Clinic intelligent mouthguard: a new technology to accurately measure head impact in athletes and soldiers. Proceedings of SPIE 8723, Sensing Technologies for Global Health, Military Medicine, and Environmental Monitoring III. 2013;8723:1-8.

Camarillo DB, Shull PB, Mattson J, Shultz R, Garza D. An instrumented mouthguard for measuring linear and angular head impact kinematics in American football. Ann Biomed Eng. 2013 Sep;41(9):1939-49.

Head Kinematics Estimates CRF Module Instructions

Cortes N, Lincoln AE, Myer GD, Hepburn L, Higgins M, Putukian M, Caswell SV. Video Analysis Verification of Head Impact Events Measured by Wearable Sensors. Am J Sports Med. 2017 Aug;45(10):2379-2387.

Wu LC, Zarnescu L, Nangia V, Cam B, Camarillo DB. A head impact detection system using SVM classification and proximity sensing in an instrumented mouthguard. IEEE Trans Biomed Eng. 2014 Nov;61(11):2659-68.

Table 2 – Sports and Positions

Baseball		Base Coach	Biking		Rider		
		Base Runner		Bowling		Participant	
		Batter			Boxing		102lbs
		Catcher					105lbs
		Center Field					108lbs
		First Base					112lbs
		Left Field					115lbs
		Participant					118lbs
		Pitcher					122lbs
		Right Field					126lbs
		Second Base					130lbs
		Short Stop					135lbs
		Third Base					140lbs
	Basketball					Center	
		Forward					154lbs
		Guard					160lbs
		Participant					168lbs
Beach Volleyball		Participant		175lbs			
				200lbs			

Head Kinematics Estimates CRF Module Instructions

		Heavyweight			Midfielder
		Participant			Participant
Cheerleading		Base	Football		Center
		Flyer			Cornerback
		Back Spotter			Defensive End
		Front Spotter			Defensive Tackle/Nose Guard
		Participant			Defensive Back
		Unknown			Flanker/Wide Receiver
Cross Country/ Track		Runner			Holder
		Unknown			Punter/Kicker
Diving		Diver			Linebacker
Fencing		Participant			Long Snapper
Field		Decathlete			Off (tight) End Tight End
		Heptathlete			Off Guard
		Jumper			Off Tackle
		Pentathlete			Quarterback
		Runner			Running Back/ Slot Fullback
		Thrower			Safety
		Participant			Special Teams (FG Offense)
		Pole Vaulter			Special Teams (FG Defense)
Field Hockey		Defensive Back		Special Teams (Punt Return)	
		Forward/Attack		Special Teams (Punt Coverage)	
		Goalkeeper			

Head Kinematics Estimates CRF Module Instructions

		Special Teams (Kickoff Coverage)	Lacrosse		Defensive Back
		Special Teams (Kickoff Return)			Forward Attack
		Participant			Goal Keeper
					Middlefield
Golf		Participant	Rifle		Participant
Gymnastics		Participant	Rowing/Crew		Coxwain
Ice Hockey		Center			Port
		Defense Right			Starboard
		Defense Left			Participant
		Forward Attack			Unknown
		Goal Keeper	Rugby		Loosehead Prop
		Participant			Hooker
		Wing (left)			Tighthead Prop
		Wing (right)			Second Row
In Line Hockey		Center			Blindside Flanker
		Defense Right			Openside Flanker
		Defense Left			Number 8
		Forward Attack			Scrum-half
		Goal Keeper			Fly-half
		Participant			Inside Center
		Wing (left)			Outside Center
		Wing (right)			Left Wing
		Other			Fullback

Head Kinematics Estimates CRF Module Instructions

	Participant		Sprint Football	Center
	Unknown			Cornerback
Sailing	Participant			Defensive End
Skiing	Alpine			Defensive Tackle/Nose Guard
	Cross Country			Defensive Back
	Participant			Flanker/Wide Receiver
Soccer	Defensive Back			Holder
	Forward			Punter/Kicker
	Goalkeeper			Linebacker
	Midfielder			Long Snapper
Softball	Base Coach			Off (tight) Tight End
	Base Runner			Off Guard
	Batter			Off Tackle
	Catcher			Quarterback
	Center Field			Running Back/ Slot Fullback
	First Base			Safety
	Left Field			Special Teams (FG Offense)
	Participant			Special Teams (FG Defense)
	Pitcher			Special Teams (Punt Return)
	Right Field			Special Teams (Punt Coverage)
	Second Base			Special Teams (Kickoff Coverage)
	Short Stop			Special Teams (Kickoff Return)
	Third Base			

Head Kinematics Estimates CRF Module Instructions

		Participant			165 lbs
		Other			174 lbs
Squash		Singles			184 lbs
		Doubles			197 lbs
		Participant			Heavyweight
Swimming		Swimmer			Participant
Tennis		Doubles	Other, specify		
		Singles			
		Participant			
Volleyball		Libero			
		Middle Blocker			
		Outside Hitter			
		Setter			
		Participant			
		Opposite/Right side Hitter			
Water Polo		Goalkeeper			
		Swimmer			
		Participant			
Wrestling		125 lbs			
		133 lbs			
		141 lbs			
		149 lbs			
		157 lbs			

Height and Weight

[Study Name/ID pre-filled]

Site Name:

Participant ID:

Visit Date:

Visit Name:

1. Head circumference:

☐ Inches ☐ Centimeters

2. Weight:

☐ Pounds ☐ Kilograms

3. Method for measuring weight Measurement Type:

☐ Self-reported ☐ Measured

4. Height:

☐ Inches ☐ Centimeters ☐ Meters ☐ Feet

5. Method for measuring height:

☐ Self-reported ☐ Measured

Recorder Signature:

TBI CDE Version 3.1

Date:

Initials:

Page 1 of 3

Height and Weight CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) collects the head circumference, height, and weight of the study participant at the time of enrollment.

Important note: None of the data elements included on this CRF Module are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies).

All the data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study design and type(s).

The Supplemental CDEs are applicable to the following study designs: Clinical Trials, Observational Studies, Comparative Effectiveness Studies, and Epidemiologic Studies.

The data elements on this CRF Module are part of the NINDS CDE Assessments and Examinations Domain.

Additional details regarding classification definitions are available: [\[Link to be added once available.\]](#)

Please see the Data Dictionary for element classifications.

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Head circumference – Record the head circumference of the participant. To be collected at the visit, not self-reported.
- Head circumference unit of measure – Choose one. Indicate whether the head circumference was collected in inches or centimeters.
- Weight – Record the weight of the participant. To be collected at the visit, not self-reported. If the participant is in a wheelchair, measure the weight of the participant plus the wheelchair, then the weight of the wheelchair alone to get the weight of the individual. The suggested range is 0-500 kg or 0-1000 lbs. Height and weight can be measured or estimated upon admission, or alternatively information may be obtained from relatives. Add date stamp for when assessed. Recommend collection at least on date of TBI. Documentation of height and weight is motivated by two reasons: 1. the risk of (systemic) complications is greater in the presence of obesity; 2. body weight is important for calculating required doses of (study) medications.
- Weight unit of measure – Choose one. Indicate whether the weight was collected in pounds or kilograms.
- Method for measuring weight – Choose one. Height and weight can be measured or estimated upon admission, or alternatively information may be obtained from relatives. Documentation of height and weight is motivated by two reasons: 1. the risk of (systemic) complications is greater in the presence of obesity; 2. body weight is important for calculating required doses of (study) medications.
- Height – The suggested range is 0-500 cm or 0-100 inches. Height and weight can be measured or estimated upon admission, or alternatively information may be obtained from relatives. Add date stamp for when assessed. Documentation of height and weight is motivated by two reasons: 1. the risk of (systemic) complications is greater in the presence of obesity; 2. body weight is important for calculating required doses of (study) medications.
- Height unit of measure – Choose one. Indicate whether the height was collected in inches, centimeters, meters, or feet.
- Method for measuring height – Choose one. Height and weight can be measured or estimated upon admission, or alternatively information may be obtained from relatives. Documentation of height and weight is motivated by two reasons: 1. the risk of (systemic) complications is greater in the presence of obesity; 2. body weight is important for calculating required doses of (study) medications.

Height and Weight CRF Module Instructions

REFERENCES

Pryor HB, Thelander H. Abnormally small head size and intellect in children. J Pediatr. 1968 Oct;73(4):593-8.

Injury Presentation – Early/Late

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Visit Date:
Visit Name:

1. *Injury date ~~and time~~:
 - a. **Reliability of injury date (Choose one):
 - ☐ Verified
 - ☐ Estimated
 - ☐ Unknown
 - b. **If estimated, the point in time estimated as injury date (Choose one):
 - ☐ Time that the participant ~~/subject~~ became symptomatic
 - ☐ Time of first trauma activation
 - ☐ Time of presentation to emergency department
2. **Injury time:
 - a. ~~Injury time reliability type~~ **Reliability of injury time (Choose one):
 - ☐ Verified
 - ☐ Estimated
 - ☐ Unknown
3. **Symptom onset date ~~and time~~:
4. **Symptom onset time:
5. First symptom type noted:
 - ☐ Loss of consciousness (LOC)
 - ☐ Confusion
 - ☐ Headache
 - ☐ Vomiting
 - ☐ Dizziness
 - ☐ Focal signs
 - ☐ Other, specify:
 - ☐ Unknown
6. Witnessed vs. unwitnessed onset:
 - ☐ Witnessed
 - ☐ Unwitnessed
 - ☐ Unknown
7. **If first treated at a hospital prior to arriving at study center, arrival date and time:
8. Injury presentation reason:
 - ☐ On advice of significant other
 - ☐ Routine screening
 - ☐ Repatriation
 - ☐ Professional referral
 - ☐ Self-referral with complaints
9. Injury presentation professional referral category:
 - ☐ General practitioner
 - ☐ Advanced practice provider
 - ☐ Hospital staff
 - ☐ Other ~~caretaker~~ professional

Injury Presentation – Early/Late

[Study Name/ID pre-filled]

Site Name:
Participant ID:

PRE-HOSPITAL CARE

10. Emergency medical care provider type:

- ☐ Bystander
- ☐ Trainer/coach
- ☐ Paramedic/medic
- ☐ Emergency department
- ☐ Physician
- ☐ Other

11. Emergency medical care provider training type:

- ☐ Untrained person
- ☐ Military – non medic
- ☐ Paramedic
- ☐ Nurse
- ☐ Physician
- ☐ Medical rescue team
- ☐ Other
- ☐ None

12. Were EMS activated?

- ☐ Yes
- ☐ No
- ☐ Unknown

a. If Yes, emergency service type:

- ☐ None
- ☐ Police
- ☐ Firefighter
- ☐ Ambulance (Core, EMT-B)
- ☐ Ambulance with specialized personnel (EMT-1)
- ☐ Helicopter medical service
- ☐ Other, specify:

b. If Yes, emergency services response time duration:

c. If Yes, intervention before hospital arrival:

- ☐ Intubation
- ☐ IV fluids
- ☐ Sedation
- ☐ Other, specify:
- ☐ Unknown

d. The initial Glasgow Coma Scale (GCS) score at the scene and on emergency department (ED) arrival should be recorded. The Pediatric Glasgow Coma Scale (pGCS) score should be recorded for pediatric participants. Link to Notice of Copyright (NOC) documents for the GCS and pGCS are located here: [Links to be added once available.]

i. If Yes, pre-hospital GCS time:

ii. If Yes, are there confounders present that affect GCS assessment? (Choose all that apply)

- ☐ None
- ☐ Unknown
- ☐ Sedation/paralytics
- ☐ Intubation/tracheostomy
- ☐ Language barrier/aphasia
- ☐ Alcohol/drug intoxication
- ☐ Pre-existing neurologic deficits

Injury Presentation – Early/Late

[Study Name/ID pre-filled]

Site Name:
Participant ID:

- ☐ Severe facial trauma/edema
- ☐ Shock/hypothermia/metabolic derangements

e. If Yes, emergency services time at injury scene duration:

13. Transport to hospital type:

- ☐ Ground ambulance with physician
- ☐ Ground ambulance no physician
- ☐ Private transportation/taxi/other from home/scene
- ☐ By foot
- ☐ Helicopter
- ☐ Other, specify:

HOSPITAL CARE

14. **Hospital admission date and time:

15. Hospital presentation type:

- ☐ Primary (Participant Patient was taken directly from the scene of accident to the study hospital)
- ☐ Secondary (Participant Patient was first taken to a non-study hospital and then transferred to the study hospital.)

16. Study center arrival date and time:

17. The initial GCS score at the scene and on ED arrival should be recorded. The pGCS score should be recorded for pediatric participants. Links to NOC documents for the GCS and pGCS are located here: [Link to be added once available.]

a. ED arrival GCS assessment time:

b. Are there confounders present that affect the GCS assessment? (Choose all that apply)

- ☐ None
- ☐ Unknown
- ☐ Sedation/paralytics
- ☐ Intubation/tracheostomy
- ☐ Language barrier/aphasia
- ☐ Alcohol/drug intoxication
- ☐ Pre-existing neurologic deficits
- ☐ Severe facial trauma/edema
- ☐ Shock/hypothermia/metabolic derangements

18. **Were initial medical services received directly after injury? (Choose one)

- ☐ Yes
- ☐ No
- ☐ Unknown

19. *Time elapsed (in minutes) from the time of injury:

20. Injury immediate medical services received type:

- ☐ CT/MRI
- ☐ Hospitalization
- ☐ Specialized therapies (speech, physical, occupational therapy)
- ☐ Evaluations (neurological, psychological)
- ☐ Medication
- ☐ Education about course of symptoms

Recorder Signature:

Date:

Injury Presentation – Early/Late CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements that are collected to describe the participant's presentation to medical care for the injury, which may be immediately after the injury (early) or after a period of time (late).

Important note: Some of the data elements are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies) or Supplemental – Highly Recommended (i.e., strongly recommended for all study designs and certain disease conditions or study types), as indicated by asterisks below, and should be collected if the following study types are performed: acute TBI clinical studies (including studies of early clinical course or early interventions); emergency department–based TBI studies; pre-hospital / EMS TBI studies; studies evaluating early predictors of TBI severity or outcome; trauma registry or epidemiologic studies focused on injury circumstances; studies examining injury mechanism, intent, or contextual factors; longitudinal cohort studies.

*Element is classified as Disease Core

**Element is classified as Supplemental – Highly Recommended

The remaining data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study design and type(s).

The Supplemental CDEs are applicable to the following study designs: Clinical Trials, Observational Studies, Comparative Effectiveness Studies, and Epidemiologic Studies.

The data elements on this CRF Module are part of the NINDS CDE Disease/Injury Related Events Domain.

Additional details regarding classification definitions are available: [\[Link to be added once available.\]](#)

Please see the Data Dictionary for element classifications.

~~Some of the data elements are classified as Core (i.e., strongly recommended for all TBI clinical studies to collect) or Basic (i.e., essential information for specified conditions, study types, or designs), as indicated by asterisks below.~~

~~*Element is classified as Core:~~

~~Injury date time~~

~~Injury elapsed time duration~~

~~**Element is classified as Basic for Acute Hospitalized studies:~~

~~Hospital admission date and time~~

~~Injury date reliability type~~

~~Injury date time~~

~~**Element is classified as Basic for Concussion/Mild TBI studies:~~

~~Hospital admission date and time~~

~~Hospital first treat arrival date time~~

~~Injury date reliability type~~

~~Injury date time~~

~~Injury date time estimation type~~

~~Symptom onset date and time~~

~~**Element is classified as Basic for Epidemiology studies:~~

Injury Presentation – Early/Late CRF Module Instructions

~~Injury date reliability type~~

~~Injury date time~~

~~Injury immediate medical service receive indicator~~

~~For other study types these CDEs are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study.~~

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- ~~Injury date time~~ – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- Reliability of injury date – Choose one.
- If estimated, the point in time estimated as injury date – Choose one.
- Injury time – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss. Note: This information may be considered protected health information (PHI).
- Reliability of injury time – Choose one.
- ~~Symptom onset date and time~~ – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- Symptom onset time – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- First symptom type noted – Choose one. If Other, specify is chosen, specify the other first symptom type.
- Witnessed vs. unwitnessed symptom onset – Choose one.
- If first treated at a hospital prior to arriving at study center, arrival date and time – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- Injury presentation reason – Choose one.
- Injury presentation professional referral category – Choose one.
- Emergency medical care provider type – Choose all that apply.
- Emergency medical care provider training type – Choose all that apply.
- Were EMS activated? – Choose one.
- If Yes, emergency service type – Choose all that apply. If Other, specify is chosen, specify the other emergency service type.
- If Yes, emergency services response time duration – Response should be recorded in the format DD:HH:MM.
- If Yes, intervention before hospital arrival – Choose all that apply. If Other, specify is chosen, specify the other intervention(s).

Injury Presentation – Early/Late CRF Module Instructions

- If Yes, pre-hospital GCS time – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- If Yes, are there confounders present that affect GCS assessment? – Choose all that apply.
- If Yes, emergency service time at injury scene duration – Response should be recorded in the format HH:MM.
- Transport to hospital type – Choose one. If Other, specify is chosen, specify the other transport type.
- Hospital admission date and time – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- Hospital presentation type – Choose one.
- Study center arrival date and time – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- ED arrival GCS assessment time - Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- Are there confounders present that affect GCS assessment? – Choose all that apply.
- Were initial medical services received directly after injury? – Choose one.
- Time elapsed (in minutes) from the time of injury – Indicate the time since injury occurred following definition provided per protocol. Note: Accurate determination of time since injury is critical for gauging participant progress and for assessing eligibility for acute phase studies. The need for TBI participants to be transferred from an initial receiving hospital to another hospital may delay definitive care and consequently impact outcome adversely, and longer transport times delay definitive treatment.
- Injury immediate medical service received type - Choose all that apply.

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Intracranial Pressure Monitoring

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Visit Date:
Visit Name:

1. Intracranial pressure (ICP) monitoring start date and time:

2. Method of recording ICP:

- ☐ Manual recording
☐ High frequency/continuous recording

3. Frequency of ICP recording:

4. Reason ICP monitoring was stopped:

- ☐ Clinically improved/no longer required
☐ Participant considered unsalvageable/futility
☐ Participant transitioned to palliative care
☐ Monitor/catheter failure
☐ Participant died
☐ Unknown

5. Type of problem experienced during ICP monitoring:

- ☐ Catheter obstruction/~~failure~~
☐ Catheter failure
☐ Catheter misplacement/malposition
☐ Suspicion of inaccurate measurement
☐ Accidental catheter removal
☐ Other, specify:
☐ None

6. ICP monitoring stop date and time:

7. Was the ~~intracranial-pressure~~ ICP catheter ~~indicator~~ revised?

- ☐ Repositioned
☐ Replaced
☐ Not revised
☐ ~~Yes~~ ☐ ~~No~~ ☐ ~~Unknown~~

~~Intracranial-pressure catheter anatomic site~~

- ☐ ~~Intraparenchymal~~
☐ ~~Epidural~~
☐ ~~Intraventricular~~
☐ ~~Subdural~~
☐ ~~Other, specify:~~

8. ICP catheter location:

- ☐ Normal-appearing tissue
☐ Perilesional
☐ Intralesional
☐ Other, specify:

9. If external ventricular drain was used for ICP monitoring, indicate anatomic landmark for levelling:

- ☐ Phlebostatic axis, or the level of the right atrium
☐ Tragus
☐ Other, specify:

Intracranial Pressure Monitoring

[Study Name/ID pre-filled]

Site Name:
Participant ID:

10. ~~Intracranial pressure~~ ICP device type:

- ☐ Intraparenchymal
- ☐ Ventriculostomy
- ☐ Other, specify:

11. ~~Intracranial pressure~~ ICP measurement (mmHg):

12. Threshold for ICP treatment:

13. Time ICP exceeded treatment threshold:

~~Intracranial pressure maximum daily measurement (mmHg):~~

~~Intracranial pressure mean daily measurement (mmHg):~~

~~Intracranial pressure episodes greater than 20 mmHg lasting longer than five minutes:~~

~~Intracranial pressure episodes greater than 20 mmHg:~~

14. Cerebral perfusion pressure (CPP) value (mmHg):

15. Threshold for treating CPP:

16. Time CPP was less than treatment threshold:

~~Cerebral perfusion pressure episodes lower than 60 mmHG:~~

It is recommended that the Therapy Intensity Level (TIL) scale be completed whenever this CRF is completed.
The TIL scale is pending review.

Recorder Signature:

Date:

Intracranial Pressure Monitoring CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements related to monitoring intracranial pressure (ICP).

Important note: None of the data elements included on this CRF Module are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies).

All the data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study design and type(s).

The Supplemental CDEs are applicable to the following study designs and types: Clinical Trials, Observational Studies, and Comparative Effectiveness Studies involving severe TBI patients during the early post-injury period.

The data elements on this CRF Module are part of the NINDS CDE Assessments and Examinations Domain.

Additional details regarding classification definitions are available: [Link to be added once available.]

Please see the Data Dictionary for element classifications.

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Intracranial pressure (ICP) monitoring start date and time – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- Method of recording ICP – Indicate whether ICP was recorded manually or via an electronic capture system such as the Moberg CNS monitor or ICM+.
- Frequency of ICP – Provide the frequency of the ICP recording. For manually recorded ICP, recommend recording at least once an hour. For high frequency data, ideally provide the entire serial ICP data. The serial ICP data can then be summarized as required by individual studies, and can be related to therapies that are provided to lower ICP. Recent studies have suggested that the amount of therapy required to control ICP, as provided by the Therapy Intensity Level or TIL, may be a better reflection of the severity of intracranial hypertension than the ICP.
- Reason ICP monitoring was stopped – Choose one. Documentation of the reason for stopping monitoring is relevant when interpreting measured values and their relation to therapy intensity.
- Type of problem experienced during ICP monitoring – Choose all that apply. Recommend collection on a daily basis. Measured values may be influenced by catheter malfunction. It is therefore highly important to document possible problems in ICP monitoring. If other problem occurred, specify the problem.
- ICP monitoring stop date and time – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- Was the ICP catheter revised? – Choose one. To be completed on a daily basis. Measured values may be influenced by catheter malfunction. It is therefore highly important to document possible problems in ICP monitoring.
- ~~Intracranial pressure catheter anatomic site – Choose one. The reliability and comparability of measured values may in part depend on the device used.~~

Intracranial Pressure Monitoring CRF Module Instructions

- ~~Intracranial pressure catheter anatomic site other text – Choose one. The reliability and comparability of measured values may in part depend on the device used.~~
- ICP catheter location – Choose one. If Perilesional is selected, select one location as best judged by radiographic evidence. If other location, specify location.
- If external ventricular drain used for ICP monitoring, indicate anatomic landmark for levelling – Choose one. If other anatomic landmark, specify anatomic landmark.
- ICP device type – Choose one. The reliability and comparability of measured values may in part depend on the device used. If other device type is used, specify the device type.
- ~~Intracranial pressure device other text – Choose one. The reliability and comparability of measured values may in part depend on the device used.~~
- ICP measurement (mmHg) – Recommend collection during acute hospital care. The recommended reference range is -10 to 300 mmHg. Add date/time stamp as well as time after injury for when assessed. Ideally the raw serial data is provided when ICP is collected using a high frequency/continuous method. When ICP data is recorded hourly, we recommend recording the maximum ICP that occurred for at least 5 minutes during the hour. For valid comparison of results between participants and across studies, a common approach towards zeroing the ICP monitor should be agreed upon. For fluid coupled systems we suggest that the ICP monitor be zeroed to the level of the foramen of Monro.
- Threshold for ICP treatment – Enter the ICP threshold that was used in the study to initiate treatment.
- Time ICP exceeded treatment threshold – Record the duration of time that ICP exceeded the treatment threshold during each 24 hour period.
- ~~Intracranial pressure maximum daily measurement – The suggested range is -10 to 300 mmHg. Recommend collection during acute hospital care. Add date stamp for when assessed. It is recommended to document the highest ICP, zeroing the ICP monitor at the level of the foramen of Monro and to relate all hourly data to date and time of injury, as being the only fixed time event across patients. Monitoring for and treating raised ICP is an important element in the management of patients with severe TBI. Pediatric-specific notes: As a minimum, vital signs should be recorded on admission and further, on a daily basis during the acute phase after injury. For the Core datasets, we recommend recording the average and lowest blood pressure over a given period. In the ICU environment, recording blood pressure on an hourly basis is recommended, especially when intracranial pressure (ICP) is monitored in order to permit determination of CPP, calculated as mean arterial blood pressure (MABP) – ICP (intermediate data set). For valid comparison of results between patients and across studies, a common approach towards zeroing the ICP monitor should be agreed upon. For fluid coupled systems we suggest that the ICP monitor be zeroed to the level of the foramen of Monro.~~
- ~~Intracranial pressure mean daily measurement – The suggested range is -10 to 300 mmHg. Recommend collection during acute hospital care. Add date stamp for when assessed. Record the average ICP on a daily basis. The average does not need to be the mathematical average of multiple measurements, but rather the value most representative of this 'daily' period. It is recommended to zero the ICP monitor at the level of the foramen of Monro and to relate all hourly data to date and time of injury, as being the only fixed time event across patients. Monitoring for and treating raised ICP is an important element in the management of patients with severe TBI.~~
- ~~Intracranial pressure episode greater 20 mmHg longer 5 minutes count – Recommend collection during acute hospital care. Add date stamp for when assessed.~~
- ~~Intracranial pressure episode greater 20 mmHg count – Recommend collection during acute hospital care. Add date stamp for when assessed.~~
- Cerebral perfusion pressure (CPP) value (mmHg) – Calculate CPP using the formula $CPP = MABP - ICP$. This element is recommended for pediatric studies. In the ICU environment, recording blood pressure on an hourly basis is recommended, especially when intracranial pressure (ICP) is monitored in order to permit determination of CPP, calculated as mean arterial blood pressure (MABP) – ICP (supplemental data set). Ideally the raw serial data is provided when CPP is collected using a high frequency/continuous method. When CPP data is recorded hourly, we recommend recording the lowest CPP that occurred for at least 5 minutes during the hour.

Intracranial Pressure Monitoring CRF Module Instructions

- ~~• Cerebral perfusion pressure episodes lower 60 mmHg number – Recommend collection during acute hospital care. Add date stamp for when assessed.~~
- Threshold for treating CPP – Enter the CPP threshold that was used in the study to initiate treatment.
- Time CPP was less than treatment threshold – Record the duration of time that CPP was less than the treatment threshold during each 24 hour period.

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Guidelines for the Management of Severe TBI, 4th edition. Chapter 13 Cerebral perfusion pressure monitoring. <https://braintrauma.org/coma/guidelines/severe-tbi>

Intracranial Pressure Monitoring CRF Module Instructions

Guidelines for the Management of Severe TBI, 4th edition. Chapter 16. Intracranial pressure thresholds.
<https://braintrauma.org/coma/guidelines/severe-tbi>

Guidelines for the Management of Severe TBI, 4th edition. Chapter 17. Cerebral perfusion pressure thresholds.
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Second Insults and Other Complications

[Study Name/ID pre-filled]

Site Name:

Participant ID:

Visit Date:

Visit Name:

1. ****Time of assessment:**

Answer 'Yes' to any of the symptom episode questions below if the episode occurred since the last time of assessment.

2. ****Did participant experience hypotensive episode? (Choose one)**

☐ Yes ☐ No ☐ Suspected ☐ Unknown

3. ****Did participant experience hypoxic episode? (Choose one)**

☐ Yes ☐ No ☐ Suspected ☐ Unknown

4. ****Did participant experience cardiac arrest? (Choose one)**

☐ Yes ☐ No ☐ Suspected ☐ Unknown

5. ****Did participant experience seizure(s)? (Choose one)**

☐ Yes ☐ No ☐ Suspected ☐ Unknown

a. Presentation of seizure (Choose one): ☐ Convulsive ☐ Non-convulsive

b. Seizure TBI duration type: ☐ Intermittent ☐ Status epilepticus

6. EEG monitoring type: ☐ Routine ☐ Continuous/prolonged

Additional Supplemental Elements:

~~These elements may be included if relevant to the study. For additional details like permissible values, see the data dictionary associated with this CRF.~~

7. ****Did participant experience hypertension? Hypertension indicator (Choose one)**

☐ Yes ☐ No ☐ Suspected ☐ Unknown

8. ****Did participant experience hypothermia? Hypothermia indicator (Choose one)**

☐ Yes ☐ No ☐ Suspected ☐ Unknown

9. ****Did participant experience hyperthermia? Hyperthermia indicator (Choose one)**

☐ Yes ☐ No ☐ Suspected ☐ Unknown

10. **Did participant experience inadvertent-hypocapnia episode? Inadvertent-hypocapnia indicator (Choose one)**

☐ Yes ☐ No ☐ Suspected ☐ Unknown

a. (If Yes or Suspected) Hypocapnia episode type: ☐ Inadvertent ☐ Intentional

11. **Did participant experience hypercapnia episode? (Choose one)**

☐ Yes ☐ No ☐ Suspected ☐ Unknown

~~Did participant/subject experience hyperventilation? Hyperventilation indicator (Choose one)~~

~~☐ Yes ☐ No ☐ Suspected ☐ Unknown~~

12. **Did participant experience an aspiration of foreign materials event? Aspiration indicator (Choose one)**

☐ Yes ☐ No ☐ Suspected ☐ Unknown

13. **Did participant experience an acute hemoglobin drop? (Choose one)**

☐ Yes ☐ No ☐ Unknown

Recorder Signature:

Date:

Second Insults and Other Complications CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements that are collected to describe insults and complications the participant experienced secondary to the injury. The CRF should be used during hospitalization for acute and chronic TBI.

Important note: None of the data elements included on this CRF Module are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies). Most of the data elements are classified as Supplemental – Highly Recommended (i.e., strongly recommended for all study designs and certain disease conditions or study types), as indicated by asterisks below.

****Element is classified as Supplemental – Highly Recommended**

The remaining data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study design and type(s).

The Supplemental CDEs are applicable to the following study designs: Clinical Trials, Observational Studies, Comparative Effectiveness Studies, and Epidemiologic Studies.

The data elements on this CRF Module are part of the NINDS CDE Disease/Injury Related Events Domain.

Additional details regarding classification definitions are available: [\[Link to be added once available.\]](#)

Please see the Data Dictionary for element classifications.

~~Some of the data elements are classified as Basic (i.e., essential information for specified conditions, study types, or designs), as indicated by asterisks below.~~

~~**Element is classified as Basic for Acute Hospitalized studies:~~

~~Hypotensive episode indicator~~

~~Hypoxic episode indicator~~

~~Cardiac arrest indicator~~

~~**Element is classified as Basic for Concussion/Mild TBI studies:~~

~~Seizure indicator~~

~~Seizure presentation type~~

~~For other study types these CDEs are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study.~~

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Time of assessment – Enter the time of assessment of second insults and other complications. Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format

Second Insults and Other Complications CRF Module Instructions

specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss. Answer 'Yes' to any of the symptom episode questions below if the episode occurred since the last time of assessment.

- Did participant experience hypotensive episode? – Choose one. This is an indicator of a hypotensive episode that is likely to result in neurological harm.
 - In adults, there is increasing evidence that the past hypotension threshold of a systolic blood pressure (SBP) of 90 mmHg is too low. Several recent studies have suggested that SBP levels lower than 110-130 mmHg may be associated with worse outcomes. Given the evolving knowledge in this area, and recognizing that the TQIP TBI Guidelines (<https://www.facs.org/media/vgfgjpfk/best-practices-guidelines-traumatic-brain-injury.pdf>) recommend maintaining a SBP > 110 mmHg, this CRF currently defines a hypotensive episode in adults as a SBP < 110 mmHg, with a plan for regular review as evidence emerges.
 - In children, a hypotensive episode is defined (<https://doi.org/10.1080/10903127.2023.2187905>) as systolic blood pressure < 75th-90th percentile of normal for age. Systolic blood pressure targets are as follows:
 - 28 days and younger > 70 mmHg
 - 1–12 months > 84 mmHg
 - 1–5 years > 90 mmHg
 - 6 years and older > 100 mmHg
- Did participant experience hypoxic episode? – Choose one. Indicator of hypoxic episode. Hypoxic episode is defined as partial pressure of oxygen in the blood (paO₂) < 8kPa (60 mmHg) or oxygen saturation (SaO₂) < 90%.
- Did participant experience cardiac arrest? – Choose one. ~~This element is recommended for pediatric studies. Second insults may aggravate processes of secondary damage in a brain already rendered vulnerable by the primary injury. The main physiologic insults relevant to TBI are hypotension, hyper- or hypothermia, hypoxia, and hypocapnia due to hyperventilation. The adverse effect of the occurrence of such insults both pre- and in-hospital is well established. Second insults are commonly defined by threshold values but these values are not well established in pediatrics. Based on the available data for pediatric TBI, thresholds of 80–180 mg/dL for glucose are recommended. A threshold for hemoglobin is more difficult to define given emerging data on the lower limit of hemoglobin safely tolerated by critically ill children in general and the variable effect of blood transfusion in children with severe TBI specifically.~~
- Did participant experience seizure(s)? – Choose one. Seizure activity in the brain may cause focal or generalized vasodilation with increased cerebral blood volume and high intracranial pressure. Moreover, metabolic requirements are increased in a situation where brain metabolism is already compromised. Seizures are therefore an important second insult following TBI.
- Presentation of seizure – Choose one. ~~This element is only answered if the participant had a seizure. This element is recommended for pediatric studies. Second insults are commonly defined by threshold values but these values are not well established in pediatrics. Based on the available data for pediatric TBI, thresholds of 80–180 mg/dL for glucose are recommended. A threshold for hemoglobin is more difficult to define given emerging data on the lower limit of hemoglobin safely tolerated by critically ill children in general and the variable effect of blood transfusion in children with severe TBI specifically.~~
- Seizure duration type – Choose one. ~~This element is only answered if the participant had a seizure. This element is recommended for pediatric studies.~~
- EEG monitoring type – Choose one. Response is obtained from medical charts and/or patient data management system. ~~This element is recommended for pediatric studies.~~
- Did participant experience hypertension? – Choose one. Defined as MAP > 90 mmHg. ~~This element is recommended for pediatric studies. Second insults may aggravate processes of secondary damage in a brain already rendered vulnerable by the primary injury. The main physiologic insults relevant to TBI are hypotension, hyper- or hypothermia, hypoxia, and hypocapnia due to hyperventilation. The adverse effect of the occurrence of such insults both pre- and in-hospital is well established. Second insults are commonly defined by threshold values but these values are not well established in pediatrics. Based on the available data for pediatric TBI, thresholds of 80–180 mg/dL for glucose are recommended. A threshold for hemoglobin is more difficult to define given emerging data on the lower limit of hemoglobin safely tolerated~~

Second Insults and Other Complications CRF Module Instructions

by critically ill children in general and the variable effect of blood transfusion in children with severe TBI specifically.

- Did participant experience hypothermia? – Choose one. Defined as core temperature $< 36^{\circ}\text{C}$. Add date stamp for when assessed. Recommend collection at least during initial medical treatment. Second insults may be systemic (extracranial or intracranial). Second insults aggravate processes of secondary damage in a brain already rendered vulnerable by the primary injury. The occurrence of second insults occurring before hospital admission in patients with more severe injuries, is frequent: oxygen saturation below 90% is found in 44 to 55% of cases and hypotension in 20 to 30%. The occurrence of second insults is strongly associated with poorer outcome. Hypoxia, hypotension and inadvertent hypocapnia are the most frequent causes of jugular desaturations, and periods of low brain tissue oxygen tension. The depth and duration of systemic second insults during the clinical course is related to poorer outcome.
- Did participant experience hyperthermia? – Choose one. Defined as core temperature $> 38^{\circ}\text{C}$. This element is recommended for pediatric studies. Second insults may aggravate processes of secondary damage in a brain already rendered vulnerable by the primary injury. The main physiologic insults relevant to TBI are hypotension, hyper- or hypothermia, hypoxia, and hypocapnia due to hyperventilation. The adverse effect of the occurrence of such insults both pre- and in-hospital is well established. Second insults are commonly defined by threshold values but these values are not well established in pediatrics. Based on the available data for pediatric TBI, thresholds of 80–180 mg/dL for glucose are recommended. A threshold for hemoglobin is more difficult to define given emerging data on the lower limit of hemoglobin safely tolerated by critically ill children in general and the variable effect of blood transfusion in children with severe TBI specifically.
- Did participant experience hypocapnia episode? – Choose one. Defined as $\text{PaCO}_2 < 35 \text{ mmHg}$ and specify as to whether this was inadvertent or therapeutic (i.e., for the purposes of ICP control). Response obtained from medical charts and/or patient data management system. Add date stamp for when assessed. Recommend collection at least during initial medical treatment. Many types of second insults may occur in the in-hospital situation, both systemic and intracranial. Systemic second insults may for example also include episodes of hypoglycemia, hyponatremia, hypernatremia, hyperthermia and many more. We chose to recommend to document the clinically most relevant and frequently occurring second insults: hypoxia, hypotension, inadvertent hypocapnia and seizure activity. Hypoxia, hypotension and inadvertent hypocapnia are the most frequent causes of jugular desaturations, and periods of low brain tissue oxygen tension. The depth and duration of systemic second insults during the clinical course is related to poorer outcome. In the intensive care environment with continuous monitoring, accurate detection of the number and duration of episodes of second insults should be possible. Thus permitting an accurate documentation of the number, depth and duration of these insults individually and summated per insult over a given period. Unfortunately, most commercially available monitoring systems do not include dedicated software to facilitate this approach. We therefore recommend to simply document the occurrence of second insults, differentiating single episodes of short duration from multiple episodes or those of more prolonged duration, as these latter may have more profound effects in aggravating secondary brain damage. Pediatric specific notes: Second insults are commonly defined by threshold values but these values are not well established in pediatrics. Based on the available data for pediatric TBI, thresholds of 80–180 mg/dL for glucose are recommended. A threshold for hemoglobin is more difficult to define given emerging data on the lower limit of hemoglobin safely tolerated by critically ill children in general and the variable effect of blood transfusion in children with severe TBI specifically.
- Hypocapnia episode type – If Yes or Suspected is selected for 'Did participant experience hypocapnia episode?', choose one. Intentional is defined when a physician-directed ventilation modification resulting in hypocapnia with the purpose of physiologic change yielding anticipated benefit to the participant.
- Did participant experience hypercapnia episode? – Choose one. Defined as $\text{PaCO}_2 > 45 \text{ mmHg}$
- Hyperventilation indicator – Choose one. Response is obtained from medical charts and/or patient data management system.
- Did participant experience an aspiration event? – Choose one. Response is obtained from medical charts and/or patient data management system. This element is recommended for pediatric studies. Second insults may aggravate processes of secondary damage in a brain already rendered vulnerable by the primary injury. The main physiologic insults relevant to TBI are hypotension, hyper- or hypothermia,

Second Insults and Other Complications CRF Module Instructions

~~hypoxia, and hypocapnia due to hyperventilation. The adverse effect of the occurrence of such insults both pre- and in-hospital is well established. Second insults are commonly defined by threshold values but these values are not well established in pediatrics. Based on the available data for pediatric TBI, thresholds of 80–180 mg/dL for glucose are recommended. A threshold for hemoglobin is more difficult to define given emerging data on the lower limit of hemoglobin safely tolerated by critically ill children in general and the variable effect of blood transfusion in children with severe TBI specifically.~~

- Did participant experience an acute hemoglobin drop? – Choose one. Yes should be answered if any of the following criteria are met: acute hemoglobin drop, a transfusion was necessary, or a clinical bleeding event occurs. Time frame from admission and percent drop in hemoglobin units should be considered. Response is obtained from medical charts and/or patient data management system. ~~This element is recommended for pediatric studies.~~

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Type, Place, Cause and Mechanism of Injury

[Study Name/ID pre-filled]

Site Name:
Participant ID:

Visit Date:
Visit Name:

1. *Type of ~~TBI~~ injury:

- | | |
|---|--|
| <input type="checkbox"/> Closed | <input type="checkbox"/> Penetrating - perforating |
| <input type="checkbox"/> Blast | <input type="checkbox"/> Penetrating - tangential |
| <input type="checkbox"/> Penetrating | <input type="checkbox"/> Crush |
| <input type="checkbox"/> Penetrating with open depressed skull fracture | <input type="checkbox"/> Unknown |

2. *~~Injury place of occurrence type~~ Place of injury:

- | | |
|---|--|
| <input type="checkbox"/> Street/highway | <input type="checkbox"/> Sport/recreation |
| <input type="checkbox"/> Public location (e.g. bar, station, nightclub) | <input type="checkbox"/> Military deployment |
| <input type="checkbox"/> Home/domestic | <input type="checkbox"/> **Other, specify: |
| <input type="checkbox"/> Work/school | <input type="checkbox"/> Unknown |

3. *Area of injury:

- ☐ Urban (city)
☐ Rural
☐ Unknown

4. *Cause of injury:

- | | |
|---|---|
| <input type="checkbox"/> Road traffic incident | <input type="checkbox"/> Act of mass violence |
| <input type="checkbox"/> Incidental fall | <input type="checkbox"/> Suicide attempt |
| <input type="checkbox"/> Other non-intentional injury | <input type="checkbox"/> **Other, specify: |
| <input type="checkbox"/> Violence/assault | <input type="checkbox"/> Unknown |

~~**Cause of TBI (Choose all that apply from codelist and/or fill in appropriate ICD-9 CM e codes below)~~

- ☐ ~~Railway accidents (e800-e807)~~
☐ ~~Motor vehicle traffic accidents (e810-e819)~~
☐ ~~Motor vehicle nontraffic accidents (e820-e825)~~
☐ ~~Other road vehicle accidents (e826-e829)~~
☐ ~~Water transport accidents (e830-e838)~~
☐ ~~Air and space transport accidents (e840-e845)~~
☐ ~~Vehicle accidents not elsewhere classifiable (e846-e848)~~
☐ ~~Accidental poisoning by drugs, medicinal substances, and biologicals (e850-e858)~~
☐ ~~Accidental poisoning by other solid and liquid substances, gases, and vapors (e860-e869)~~
☐ ~~Misadventures to patients during surgical and medical care (e870-e876)~~
☐ ~~Surgical and medical procedures as the cause of abnormal reaction of patient or later complication, without mention of misadventure at the time of procedure (e878-e879)~~
☐ ~~Accidental falls (e880-e888)~~
☐ ~~Accidents caused by fire and flames (e890-e899)~~
☐ ~~Accidents due to natural and environmental factors (e900-e909)~~
☐ ~~Accidents caused by submersion, suffocation, and foreign bodies (e910-e915)~~
☐ ~~Other accidents (e916-e928)~~
☐ ~~Late effects of accidental injury (e929)~~
☐ ~~Drugs, medicinal and biological substances causing adverse effects in therapeutic use (e930-e949)~~
☐ ~~Suicide and self-inflicted injury (e950-e959)~~
☐ ~~Homicide and injury purposely inflicted by other persons (e960-e969)~~
☐ ~~Legal intervention (e970-e978)~~
☐ ~~Terrorism (e979)~~
☐ ~~Injury undetermined whether accidentally or purposely inflicted (e980-e989)~~
☐ ~~Injury resulting from operations of war (e990-e999)~~

Type, Place, Cause and Mechanism of Injury

[Study Name/ID pre-filled]

Site Name:
Participant ID:

~~and/or *ICD-9-CM e-codes:~~

~~*ICD version number: ☐ 9 ☐ 10 ☐ 11~~

5. *Intention:

- ☐ Intentional
- ☐ Unintentional
- ☐ Undetermined

6. *Mechanism of ~~TBI~~ injury (Choose all that apply):

If "closed" head injury:

- ☐ High velocity trauma
(acceleration/deceleration)
- ☐ Blast
- ☐ Crush
- ☐ Direct impact: blow to head
- ☐ Direct impact: head against object
- ☐ Ground level fall
- ☐ Fall from height (> 1 m (3 ft) / 5 stairs)

If penetrating TBI:

- ☐ Gunshot wound
- ☐ Fragment (including shell/shrapnel)
- ☐ **Other penetrating injury, **specify:**

ROAD TRAFFIC AND MOTORIZED VEHICLE INCIDENTS

7. ~~** Traffic accident self role type~~ Road traffic or motorized vehicle incident participant role:

- ☐ Pedestrian
- ☐ Cyclist
- ☐ Moped/scooter
- ☐ Motorcycle/Motorbike
- ☐ Other, specify:
- ☐ Motor vehicle occupant:
 - ☐ Driver
 - ☐ Front seat passenger
 - ☐ Back seat passenger

8. ~~Traffic accident other party role type~~ **Road traffic or motorized vehicle incident other party:

- ☐ Yes
- ☐ No
- ☐ Unknown

a. (If Yes)** Road traffic or motorized vehicle incident other party role:

- ☐ Motor vehicle
- ☐ Pedestrian
- ☐ Cyclist
- ☐ Moped/scooter
- ☐ Motorcycle/Motorbike
- ☐ Tram/Bus
- ☐ Train/Metro
- ☐ Obstacle
- ☐ Lorry (camion)
- ☐ ~~No other party~~
- ☐ Unknown

SAFETY

9. **Protective devices used **indicator**:

- ☐ Yes
- ☐ No
- ☐ Unknown

10. **Helmet (If Cyclist or Moped/Scooter):

- ☐ Yes
- ☐ No
- ☐ Unknown

11. **Airbag (If Motor vehicle occupant):

- ☐ Yes

Type, Place, Cause and Mechanism of Injury

[Study Name/ID pre-filled]

Site Name:
Participant ID:

- ☐ No
☐ Unknown

12. **Seatbelt (If Motor vehicle occupant):

- ☐ Yes
☐ No
☐ Unknown

~~**Vehicular protective devices type~~

- ☐ ~~Helmet~~
☐ ~~Child safety restraint~~
☐ ~~Seat belt~~

- ☐ ~~Airbag~~
☐ ~~Other, specify:~~

~~**Airbag deployed indicator~~

- ☐ ~~Yes~~
☐ ~~No~~

- ☐ ~~Not applicable~~
☐ ~~Unknown~~

MOTOR VEHICLE OCCUPANTS

13. **Ejected from vehicle (If Motor vehicle occupant):

- ☐ Yes
☐ No
☐ Unknown

VIOLENCE

14. **Injury violent cause type:

- ☐ Robbery/assault
☐ Domestic assault
☐ Interpersonal violence (fight)
☐ Child abuse

- ☐ Gang violence
☐ Military deployment
☐ **Other, specify:
☐ Unknown

15. **Likelihood that injury was due to abusive head trauma? (Choose one)

- ☐ No concern
☐ Possible abuse
☐ Probable abuse
☐ Definite abuse

16. **Who has reported the head trauma from abuse?

- ☐ Child Protection Team (CPT)
☐ Pediatric Intensive Care Unit (PICU)
physician
☐ Emergency Department (ED) physician

- ☐ Police
☐ Children, Youth and Families (CYF)
☐ Coroner
☐ **Other, specify:

Type, Place, Cause and Mechanism of Injury

[Study Name/ID pre-filled]

Site Name:
Participant ID:

SPORT/RECREATION

17. **Type of sport:

Team sports:

- ☐ Football (soccer)
- ☐ Football (American)
- ☐ Field hockey
- ☐ Ice hockey
- ☐ Lacrosse
- ☐ Baseball
- ☐ Basketball
- ☐ Gymnastics
- ☐ Cheerleading
- ☐ **Other team sports, specify:

Individual contact sports:

- ☐ Boxing
- ☐ Martial arts
- ☐ **Other individual contact sports, specify:

Other sports and recreational activities:

- ☐ Rollerblading/ Skateboarding/ Scootering
- ☐ Skiing
- ☐ Snowboarding
- ☐ Hiking/climbing
- ☐ Horse riding
- ☐ Golf
- ☐ Cycling
- ☐ Off-road vehicular sports
- ☐ Watersports
- ☐ Playground activity
- ☐ **Other sports and recreational activity, specify:
- ☐ Unknown

18. **Mouthguard used:

- ☐ Yes
- ☐ No
- ☐ Unknown

BLAST

~~**Military deployment injury indicator (adult only)~~

- ☐ ~~Yes~~
- ☐ ~~No~~
- ☐ ~~Unknown~~

19. **Blast injury device type:

- ☐ Improvised Explosive Device (IED)
- ☐ Land mine
- ☐ Grenade
- ☐ Bomb
- ☐ Mortar
- ☐ Rocket Propelled Grenade (RPG)
- ☐ **Other, specify:
- ☐ Unknown

20. **Blast direction type:

- ☐ Right
- ☐ Above
- ☐ Below
- ☐ In front
- ☐ Behind
- ☐ Unknown
- ☐ Left

21. **Blast injury category:

- ☐ Primary blast (Direct effects of the detonation including the high-pressure shock front and associated blast wave and any thermal components)
- ☐ Secondary blast (Effect of flying debris or bomb fragments)
- ☐ Tertiary blast (Effect of participant being thrown from the blast wind)
- ☐ Quaternary blast (Explosion related injuries or illnesses that do not fall under primary, secondary, or tertiary blast)
- ☐ Unknown

Type, Place, Cause and Mechanism of Injury

[Study Name/ID pre-filled]

Site Name:
Participant ID:

22. **Blast enclosed space indicator:

- ☐ Yes
- ☐ No
- ☐ Unknown

23. **Biological agent exposure likelihood type:

- ☐ Suspected
- ☐ Confirmed
- ☐ Unknown
- ☐ None

24. **Chemical agent exposure likelihood type:

- ☐ Suspected
- ☐ Confirmed
- ☐ Unknown
- ☐ None

25. **Body armor indicator (adult only):

- ☐ Yes
- ☐ No
- ☐ Unknown

26. **Military combat helmet type (adult only):

- ☐ Advanced combat helmet
- ☐ Other combat helmet
- ☐ Unknown
- ☐ No

SUBSTANCE USE

27. ~~*Likelihood that subject was under the influence of alcohol?~~ Participant alcohol use:

- ☐ ~~None~~
- ☐ No
- ☐ Suspected~~ed~~
- ☐ ~~Confirmed~~
- ☐ Definite:

**Blood alcohol level: Unit: ☐ mg/dL ☐ per mil (%)

- ☐ Unknown

28. *Participant drug use:

- ☐ No
- ☐ Suspect
- ☐ Definite
- ☐ Unknown

29. **Type of drugs:

- ☐ Unknown
- ☐ Cannabis
- ☐ Cocaine
- ☐ Methamphetamines
- ☐ Opioids:

**Included on participant's medication list: ☐ Yes ☐ No

- ☐ Benzodiazepines:

Type, Place, Cause and Mechanism of Injury

[Study Name/ID pre-filled]

Site Name:
Participant ID:

****Included on participant's medication list:** ☐ Yes ☐ No

☐ ****Other, specify:**

30. ***Participant sedatives or sleeping pills use:**

- ☐ No
- ☐ Suspect
- ☐ Definite
- ☐ Unknown

31. ****Other party/parties:**

- ☐ No
- ☐ Suspect
- ☐ Definite
- ☐ Unknown

32. ****Other party alcohol use:**

- ☐ No
- ☐ Suspect
- ☐ Definite
- ☐ Unknown

33. ****Other party drugs use:**

- ☐ No
- ☐ Suspect
- ☐ Definite
- ☐ Unknown

34. ****Other party sedatives or sleeping pills use:**

- ☐ No
- ☐ Suspect
- ☐ Definite
- ☐ Unknown

~~****Traffic accident self alcohol influence likelihood type**~~

- | | |
|---|---|
| <input type="checkbox"/> Suspected | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Confirmed | <input type="checkbox"/> None |

~~****Traffic accident other party alcohol influence likelihood type**~~

- | | |
|---|---|
| <input type="checkbox"/> Suspected | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Confirmed | <input type="checkbox"/> None |

~~****Traffic accident self drug influence likelihood type**~~

- | | |
|---|---|
| <input type="checkbox"/> Suspected | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Confirmed | <input type="checkbox"/> None |

~~****Traffic accident other party drug influence likelihood type**~~

- | | |
|---|---|
| <input type="checkbox"/> Suspected | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Confirmed | <input type="checkbox"/> None |

Recorder Signature:

Date:

Type, Place, Cause and Mechanism of Injury CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements that are collected to describe the circumstances of the injury, such as how and where it occurred, and the type of injury.

Important note: The data elements on this CRF module are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies) or Supplemental – Highly Recommended (i.e., strongly recommended for all study designs and certain disease conditions or study types), as indicated by asterisks below, and should be answered as applicable based on the circumstances of the injury.

*Element is classified as Disease Core

**Element is classified as Supplemental – Highly Recommended

The data elements on this CRF Module are part of the NINDS CDE Disease/Injury Related Events Domain.

Additional details regarding classification definitions are available: [Link to be added once available.]

Please see the Data Dictionary for element classifications.

~~Some of the data elements are classified as Core (i.e., strongly recommended for all TBI clinical studies to collect) and most classified as Basic (i.e., essential information for specified conditions, study types, or designs), as indicated by asterisks below, and should be collected if Acute Hospitalized, Epidemiology, Concussion/Mild TBI, or Moderate/Severe TBI: Rehabilitation studies are performed.~~

~~*Element is classified as Core:~~

~~Injury ICD external cause code~~

~~ICD revision number~~

~~TBI cause type~~

~~**Element is classified as Basic~~

~~For other study types these CDEs are classified as Supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study.~~

~~Abusive head trauma reporter type and Abusive head trauma reporter other text are Supplemental for all study types.~~

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Type of TBI injury – Choose all that apply. Use the following abbreviated guidance when mapping TBI type to ICD 10 CM codes:
 - Assign the most specific intracranial injury code (S06- series) supported by documentation.
 - For Closed injuries: use concussion or intracranial injury codes without open wound or fracture.
 - For Blast injuries: use S06.8A (Primary blast injury of brain) when mechanism is a confirmed blast.
 - For Penetrating injuries: include both intracranial injury (S06-) and open wound/skull fracture codes (S02-) when documented.
 - For Penetrating with open depressed skull fracture: code the depressed skull fracture (open; S02-) plus intracranial injury.
 - For Perforating or Tangential penetrating injuries: assign open wound/skull fracture codes as applicable plus the appropriate S06- code.

Type, Place, Cause and Mechanism of Injury CRF Module Instructions

- For Crush injuries: use crushing injury of head codes (S07-) and intracranial injury codes if brain injury is present.
- For Unknown mechanism: use unspecified intracranial injury codes (e.g., S06.9-) only if TBI is confirmed but type is unclear.
- Always ensure documentation supports the code(s) selected. Do not over-specify when clinical information is incomplete.
- Place of injury – Choose one. The place of injury is particularly important from an epidemiologic perspective, but may also be related to mechanism of injury and consequently type and extent of brain damage.
- Area of injury – Choose one.
- Cause of injury – Choose all that apply from codelist and/or fill in appropriate ICD-9-CM e-codes below. Choose all that apply. Response is obtained from report by participant (if possible), witnesses, first responders, family and/or medical records. Different pathophysiologic mechanisms occur in different types of injury.
- ~~● Injury ICD external cause code – Record as many as needed; please refer to <http://www.cdc.gov/nchs/icd.htm> <https://www.cdc.gov/nchs/icd/icd-10-cm/>. Response is obtained from report by participant (if possible), witnesses, first responders, family and/or medical records. The cause of injury is particularly important from an epidemiologic perspective, but may also be related to mechanism of injury and consequently type and extent of brain damage.~~
- ~~● ICD revision number – Choose one.~~
- Intention - Choose one. Response is obtained from report by participant (if possible), witnesses, first responders, family and/or medical records.
- Mechanism of TBI injury – Choose all that apply. Response is obtained from report by participant (if possible), witnesses, first responders, family and/or medical records.
- Road traffic or motorized vehicle incident participant role – Choose one. Response is obtained from report by participant (if possible), witnesses, first responders, family and/or medical records. Information on the nature of the road traffic incident and the function of the participant is not only important from an epidemiological and prevention perspective, but also provides information on what type of intracranial and extracranial injuries might be expected. If Other, specify is chosen, enter other participant role.
- Road traffic or motorized vehicle incident other party – Choose one. Response is obtained from report by participant (if possible), witnesses, first responders, family and/or medical records.
- Road traffic or motorized vehicle incident other party role – If Yes is selected for 'Road traffic or motorized vehicle incident other party', choose one.
- Protective devices used indicator – Choose one. Response is obtained from report by participant (if able to provide reliable information), first responders, emergency department physicians, or medical record. ~~This element is recommended for pediatric studies.~~
- Helmet (If Cyclist or Moped/Scooter) – Choose one. Response is obtained from report by participant (if able to provide reliable information), first responders, emergency department physicians, or medical record.
- Airbag (If Motor vehicle occupant) – Choose one. Response is obtained from report by participant (if able to provide reliable information), first responders, emergency department physicians, or medical record.
- Seatbelt (If Motor vehicle occupant) – Choose one. Response is obtained from report by participant (if able to provide reliable information), first responders, emergency department physicians, or medical record.
- ~~● Vehicular protective device type – Choose all that apply. Response is obtained from report by participant/subject (if able to provide reliable information), first responders, emergency department physicians, or medical record. This element is recommended for pediatric studies.~~
- ~~● Vehicular protective device other text – Choose all that apply. Response is obtained from report by participant/subject (if able to provide reliable information), first responders, emergency department physicians, or medical record. This element is recommended for pediatric studies.~~
- ~~● Airbag deploy indicator – Choose one. Response is obtained from report by participant/subject (if able to provide reliable information), first responders, emergency department physicians, or medical record.~~

Type, Place, Cause and Mechanism of Injury CRF Module Instructions

- Ejected from vehicle (If Motor vehicle occupant) – Choose one.
- Injury violent cause type – Choose one. Response is obtained from participant (if possible), witnesses, first responders, family member or medical record.
- Likelihood that injury was due to abusive head trauma? – Choose one.
- Who has reported the head trauma from abuse? – Choose one.
- Type of sport – Choose one. If other sport chosen, enter other sport.
- Mouthguard used – Choose one.
- ~~• Military deployment injury indicator – Choose one. Response is obtained from report by participant/subject (interview, self report) or relatives. This element is intended for use in adult military populations. Severity of psychological problems has been shown to correlate with the 'severity' of combat experiences.~~
- Blast injury device type – Choose one. Response is obtained from participant (if possible), witnesses, first responders, family member or medical record.
- Blast direction type – Choose one. Response is obtained from participant (if possible), witnesses, first responders, family member or medical record.
- Blast injury category – Choose one. Response is obtained from participant (if possible), witnesses, first responders, family member or medical record.
- Blast enclosed space indicator – Choose one. Response is obtained from participant (if possible), witnesses, first responders, family member or medical record.
- Biological agent exposure likelihood type – Choose one. Response is obtained from participant (if possible), witnesses, first responders, family member or medical record.
- Chemical agent exposure likelihood type – Choose one. Response is obtained from participant (if possible), witnesses, first responders, family member or medical record.
- Body armor indicator (adult only) – Choose one. Response is obtained from participant (if possible), witnesses, first responders, family member or medical record.
- Military combat helmet type (adult only) – Choose one. Response is obtained from participant (if possible), witnesses, first responders, family member or medical record.
- Participant alcohol use – Choose one.
- Blood alcohol level – If Definite is selected for 'Participant alcohol use', enter numerical value and indicate units of mg/dL or per mil (%).
- Participant drug use – Choose one.
- Type of drugs – Choose all that apply. If Opioids or Benzodiazepines is chosen, indicate if these drugs were included on participant's medication list. If Other, specify selected, enter other type of drug(s).
- Participant sedatives or sleeping pills use – Choose one.
- Other party/parties – Choose one.
- Other party alcohol use – Choose one.
- Other party drugs use – Choose one.
- Other party sedatives or sleeping pills – Choose one.
- ~~• Traffic accident self alcohol influence likelihood type – Choose one. Response is obtained from hospital reports.~~
- ~~• Traffic accident other party alcohol influence likelihood type – Choose one. Response is obtained from hospital reports.~~
- ~~• Traffic accident self drug influence likelihood type – Choose one. Response is obtained from hospital reports.~~
- ~~• Traffic accident other party drug influence likelihood type – Choose one. Response is obtained from hospital reports.~~

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Type, Place, Cause and Mechanism of Injury CRF Module Instructions

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Video Device Confirmation

[Study Name/ID pre-filled]

Site Name:

**Participant ID:

Visit Date:

Visit Name:

1. ~~**Subject~~ ****Participant** age: (years)
2. ****Start of data collection (date / time)**
 - a. Date of first event:
 - b. Time of first event: ☐ am ☐ pm ☐ 24-hour clock
3. ****End of data collection (date / time)**
 - a. Date of last event:
 - b. Time of last event: ☐ am ☐ pm ☐ 24-hour clock
4. ****Activity (Indicate all that pertain to ~~participant~~ **subject**):**
5. ****Number of cameras:**

Answer questions 6-10 for each camera.

6. ****Camera manufacturer:**
7. ****Camera model:**
8. ****Camera resolution:**
9. ****Camera sample rate:**
10. ****Camera positions:**
11. ****Method of timestamp creation:**
12. ****Resolution of time-synchronization between video and device: (e.g. ± 1 second, ± 1 millisecond) (Note: This is different from maximum allowable DeltaT between correlated video and device exposures – see specific instructions following the questions):**
13. ****Method of time-synchronization between video and device:**
14. ****Method of cross-verifying video and device exposures:**
 - ☐ Device as ground truth
 - ☐ Video as ground truth
 - ☐ Only impacts/exposures verified in both device data and video are considered
 - ☐ Other, specify:
15. ****Method of analysis/link to correlate video and device exposures:**
 - ☐ Maximize exposure timing correlation after identifying all video and all device impacts/exposure(s)
 - ☐ Real-time stamp matching between video and device
 - ☐ Other, specify:
16. ****Maximum allowable DeltaT between correlated video and device exposures (**DeltaT- amount of time between an identified sensor/video event**):**
17. ****Number of true positive exposures (**Both video and sensor indicate an event happened within small window of time**):**

Video Device Confirmation

[Study Name/ID pre-filled]

Site Name:

**Participant ID:

18. **Number of false positive exposures (Sensor indicated an event with no verification via video within an allowable amount of time):
19. Number of false negative exposures (Video indicated an event occurred but sensor did not record one within an allowable amount of time):
20. Of the true positive exposures, number of confirmed head to head exposures:
21. Of the true positive exposures, number of confirmed head to body exposures:
22. Of the true positive exposures, number of confirmed head to ground exposures:
23. Of the true positive exposures, number of confirmed head to object exposures:
24. Of the true positive exposures, number of confirmed body exposures (with no head contact):
25. Number of events that were unable to be classified into impact source groups:
26. Analysis software:
 - ☐ ProAnalyst 3D
 - ☐ SynthEyes
 - ☐ PFTrack
 - ☐ Houdini
 - ☐ Nuke
 - ☐ Other, specify:
27. Video stabilization methods:
 - ☐ Panning
 - ☐ Zooming
 - ☐ Other, specify:

Recorder Signature:

Date:

Video Device Confirmation CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements that relate to the video confirmation of data collected via head kinematic sensors.

Important note: None of the data elements included on this CRF Module are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies). Some of the data elements are classified as Supplemental – Highly Recommended (i.e., strongly recommended for all study designs and certain disease conditions or study types), as indicated by asterisks below, and should be collected if biomechanical device studies are performed.

****Element is classified as Supplemental – Highly Recommended**

The remaining data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study design and type(s).

The Supplemental CDEs are applicable to the following study designs: Clinical Trials, Observational Studies, Comparative Effectiveness Studies, and Epidemiologic Studies.

Additional considerations include adding element to link the video clip to each impact and providing guidance on what video file type should be stored, how to facilitate the sharing of video file types, and consideration on privacy, de-identification or seeking consent for release of video clips.

The data elements on this CRF Module are part of the NINDS CDE Disease/Injury Related Events Domain.

Additional details regarding classification definitions are available: [Link to be added once available.]

Please see the Data Dictionary for element classifications.

~~Important note: The data elements noted with an asterisk (*) on this CRF Module are classified as Supplemental-Highly Recommended (i.e., strongly recommended for Biomechanical Devices in TBI clinical studies to collect). The remaining data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study. Please see the Data Dictionary for element classifications.~~

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- ~~Subject~~Participant Age – Enter participant ~~subject~~ age in years.
- Start of data collection – The date/time when data acquisition started
- Date of first ~~recorded~~ event and Time of first ~~recorded~~ event (~~hh:mm~~) – Report the time and date when the first event was recorded. Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.
- End of data collection – The date/time when data acquisition ended
- Date of last ~~recorded~~ event (~~mm/dd/yyyy~~) and Time of last ~~recorded~~ event (~~hh:mm~~) – Report the time and date when the last event was recorded. Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](#); YYYY-MM-DD T:hh:mm:ss.

Video Device Confirmation CRF Module Instructions

- Activity – Please indicate all activities under study which pertain to the **participant subject** (e.g. football, soccer)
- Number of cameras – Enter number. Answer Camera manufacturer, Camera model, Camera resolution, Camera sample rate, and Camera positions for each camera.
- Camera manufacturer – Please indicate manufacturer of video camera(s) used for recording event footage.
- Camera model – Please indicate model of video camera(s) used for recording event footage.
- Camera resolution – Please indicate resolution of video camera(s) used for recording event footage.
- Camera sample rate – Please indicate sample/frame rate of video camera(s) used for recording event footage.
- Camera positions – Please indicate positions of video camera(s) used for recording event footage. **Could include height off the ground, location relative to the field, etc.**
- Method of timestamp creation – Please indicate method of creating timestamps on video footage. The approach used to generate a timestamp for each individual video frame used to verify impacts. The timestamp is the time of day of a given video frame which will be compared with the time of day an event is recorded via the device. The timestamp can be generated by the camera using an internal clock (e.g., a GPS synched clock, an internal software clock, etc.) or can be tracked using an external source (e.g., a digital clock in view of the camera, calibrating the frames using a digital clock shown a single time, etc.). These methods are not exclusive, and other approaches may be described.
- Resolution of time-synchronization between video and device – Resolution of time-synchronization is the amount of error allowed between the device timestamp and video timestamp. Appropriate answers for this would be ± 1 second, ± 1 millisecond, etc. The resolution will depend on the accuracy of the device clock and the accuracy of the video clock (e.g., if the device timestamp is accurate to the millisecond, and the video timestamp is accurate to the second the resolution would be ± 1 second). Please indicate time resolution of time-synchronization between the video and the device. For example, if both video and device has 1 second resolution for their real-time stamps, the time resolution would be 1 second.
- Method of time-synchronization between video and device – The approach used to synchronize the timestamps of the device and video. Please ~~choose or~~ describe the method to synchronize video and device information. The time-synchronization between the device and video can be accomplished using several approaches. For example, both device and video could be synchronized with a third source (e.g., the NIST traceable time source time.gov, or localized computer time source), or they could be synchronized by forcing events on the devices in view of the camera and documenting any offsets in time. These methods are not exclusive, and other approaches may be described. The requested input is for a description of how the time-synchronization between the device and video was accomplished.
- Method of cross-verifying video and device exposures **and other text** – **Data is best described when video and data correspond (option 3).** The accelerometry device and video recording can independently capture exposure information and can be cross-verified to increase confidence of the exposure measurement. This CDE differentiates which set of information serves as the ground truth for verification. For example, if video is served as ground truth, exposures captured on video but not measured by the device would be considered as missing (false negatives). It is also an option to only consider exposures measured by both the video and the device to be 'verified' exposures. Please select from following options or, if another method is used, provide a detailed description of the method. **Indicate number and type of video reviewers (e.g., number of raters, calculations of inter- and/or intra-rater reliability, level of experience)**
- Method of analysis/link to correlate video and device exposures **and other text** – Exposures measured by the device and those observed in video need to be linked with each other for verification. For example, if a sports player was observed to sustain a head impact at 10:30:56 am on video while wearing an accelerometry device, it is expected that the accelerometry device will have a recording corresponding to this observation. The method to link the exposures could include 1) identifying the time differences between exposures in video or device and finding the time-syncing difference to maximize the correlation between the video exposure timings and device exposure timings, 2) having a timestamp for each exposure on the video or device that is synchronized with a standard real-time

Video Device Confirmation CRF Module Instructions

clock (e.g. nist.gov time) and correlating exposures via the real-time stamp. Please choose from the following options, or if another method is used, provide a detailed description of the method.

- Maximum allowable DeltaT between correlated video and device exposures – Where DeltaT is the amount of time between an identified device/video exposure(s). Due to uncertainties in real-time stamps or time offset calculations, the timing of individual exposures may not have an exact match between video and device. For example, if there is a +/- one second uncertainty in the timestamp, it is possible that a video exposure at 12:30:45 may be matched with a device exposure at 12:30:46. This CDE specifies the amount of tolerance allowed for the difference between video and device time stamps. Indicate time offset in number of seconds between video and device time stamps allowed for linking exposures.
- Number of true positive exposures – Both video and device indicate an exposure(s) happened within the allowable time-period (Maximum Allowable DeltaT - #16 above). Head impact events in which both the video and the device indicate an exposure. Through careful review of the video, identify head impact exposures. The definition of this will vary by the sport setting studied but could include identifiable change in the head kinematics (in the case of a head impact in football for example) or an identifiable change in the ball trajectory (in the case of a head to soccer ball impact). It is highly suggested that this process be conducted by multiple coders blinded to each other's efforts. Have a master coder reconcile any differences in exposure identification. Count the number of head impact events recorded on the device that can be confirmed via video. This may be tied to g-force level (e.g., impact as 25g+).
- Number of false positive exposures – Head impact exposures recorded on the device but unable to be verified by video within the allowable time-period (Maximum Allowable DeltaT - #16 above). Through careful review of the video, identify head impact exposures. The definition of this will vary by the sport setting studied but could include identifiable change in the head kinematics (in the case of a head impact in football for example) or an identifiable change in the ball trajectory (in the case of a head to soccer ball impact). It is highly suggested that this process be conducted by multiple coders blinded to each other's efforts. Have a master coder reconcile any differences in exposure identification. Count the number of head impact exposures recorded on the device that cannot be confirmed via video. This should only include those events in which the player for whom the exposure is recorded is visible on the video. It should not include unverifiable exposures out of frame of the video. This may be tied to g-force level (e.g., impact as 25g+).
- Number of false negative exposures – Head impact exposures observed on video but lacking corresponding device exposure data within the allowable time-period (Maximum Allowable DeltaT - #16 above). Through careful review of the video, identify head impact exposures. The definition of this will vary by the sport setting studied but could include identifiable change in the head kinematics (in the case of a head impact in football for example) or an identifiable change in the ball trajectory (in the case of a head to soccer ball impact). It is highly suggested that this process be conducted by multiple coders blinded to each other's efforts. Have a master coder reconcile any differences in exposure identification. Count the number of head impact exposures identified on video that do not have any corresponding data on the device within the allowable time-period.
- Of the true positive exposures, number of confirmed head to head exposures – The number of visually verified head impact events that resulted from head to head contact (including helmet to helmet contact).
- Of the true positive exposures, number of confirmed head to body exposures – The number of visually verified head impact events that resulted from head to body contact (e.g., head contacts the torso of another person).
- Of the true positive exposures, number of confirmed head to ground exposures – The number of visually verified head impact events that resulted from head to ground contact (e.g., while falling or diving, head contacts playing surface).
- Of the true positive exposures, number of confirmed head to object exposures – The number of visually verified head impact events that resulted from head to object contact (e.g., head contacts the ball).
- Of the true positive exposures, number of confirmed body exposures – The number of visually verified events in which the person's body comes in contact with another person, the ground, or an object that result in an "acceleration event" of the head – without direct contact to the head.

Video Device Confirmation CRF Module Instructions

- Number of events that were unable to be classified **into impact source groups** – These could include those events where there is device data but video data is not available (e.g. player out of frame, etc.).
- **Analysis software - Choose one. If other, specify other analysis software.**
- **Video stabilization methods - Choose all that apply. If other, specify other video stabilization method(s).**

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Vital Signs and Blood Gases

[Study Name/ID pre-filled]

Site Name:

Participant ID:

Visit Date:

Visit Name:

1. Respiratory rate (breaths per min) (0-50):
2. Heart rate (beats per min) (0-300):
3. Blood pressure (mmHg) (0-300 **systolic** / 0-300 **diastolic**):
 - a. Blood pressure measurement method:
☐ Digital cuff ☐ Manual cuff ☐ Finger cuff ☐ Arterial catheter
 - b. Daily mean value of blood pressure (mmHg) (0-300 **systolic** / 0-300 **diastolic**):
 - c. Mean Arterial Pressure (MAP) (mmHg):
4. **Pulse oximetry** oxygen saturation (%) (0-100) (daily mean measurement):
 - a. **Pulse oximetry** daily minimal value of oxygen saturation (%) (0-100):

Additional Supplemental Elements:

~~These elements may be included if relevant to the study. For additional details like permissible values, see the data dictionary associated with this CRF.~~

5. ~~Respiration type~~ Type of respiration:
☐ Spontaneous ☐ Ventilated ☐ Apneic ☐ Unknown
6. ~~Respiratory support type~~ Respiratory support device:
☐ Bag mask ventilation (BMV)
☐ ~~Intubation~~ Mechanical ventilation
☐ CPAP
☐ BiPAP
☐ No support needed
☐ ~~Oral airway~~
7. Type of airway support:
☐ Endotracheal intubation
☐ Tracheal intubation
☐ Nasal intubation
☐ Oral airway
☐ Tracheostomy
☐ Cricothyroidotomy
☐ No support needed
8. ~~Circulation support type~~ Type of circulation support:
☐ No specific therapy
☐ IV fluids – Crystalloids
☐ IV fluids – Hypertonic saline
☐ IV fluids – Colloids
☐ IV fluids – Blood
☐ Vasopressors
☐ Inotropes
☐ CPR
☐ Ventricular assistive device
☐ Other
☐ Unknown

Vital Signs and Blood Gases

[Study Name/ID pre-filled]

Site Name:
Participant ID:

9. Temperature measurement

- a. Body temperature (°C) (0-50):
- b. Maximum daily body temperature (°C) (0-50):
- c. Minimum daily body temperature (°C) (0-50):
- d. Mean daily body temperature (°C) (0-50):

10. Temperature method:

- ☐ Oral
- ☐ Rectal
- ☐ Tympanic
- ☐ Axillary
- ☐ Forehead cutaneous infrared
- ☐ Bladder
- ☐ Esophageal
- ☐ Brain
- ☐ Other, specify:
- ☐ Unknown

11. Partial pressure of oxygen in brain tissue:

ARTERIAL BLOOD GASES

12. Arterial blood oxygen saturation (%) (0-100):

~~13. Partial pressure carbon dioxide arterial measurement~~ Partial pressure of carbon dioxide in arterial blood:

~~Mean measurement of the arterial partial pressure of carbon dioxide:~~

~~14. Partial pressure oxygen arterial measurement~~ Partial pressure of oxygen in arterial blood:

~~Daily mean partial pressure of oxygen in arterial vessels:~~

15. Arterial blood pH:

VENOUS BLOOD GASES

16. Venous oxygen saturation (%) (0-100):

17. Partial pressure of carbon dioxide in venous blood:

18. Partial pressure of oxygen in venous blood:

19. Venous blood pH:

20. Unit of measure for blood gases (O₂, CO₂):

- ☐ mmHg ☐ kPa

Recorder Signature:

Date

Vital Signs and Blood Gases CRF Module Instructions

GENERAL INSTRUCTIONS

This case report form (CRF) contains data elements related to vital signs and other physiological measurements commonly used in TBI clinical research studies.

Important note: None of the data elements included on this CRF Module are classified as Disease Core (i.e., strongly recommended for all TBI clinical studies).

All the data elements are classified as Supplemental and should only be collected if the research team considers them appropriate for their study design and type(s).

The Supplemental CDEs are applicable to the following study designs and types: Clinical Trials, Observational Studies, and Comparative effectiveness studies. Vital signs and blood gas measurements are most applicable to evaluations in the early post-injury period where hypotension and hypoxia can adversely affect outcome but may also be important in monitoring in drug treatment trials and in other follow-up visit assessments. The data elements on this CRF Module are part of the NINDS CDE Assessments and Examinations Domain.

Additional details regarding classification definitions are available: [\[Link to be added once available.\]](#)

Please see the Data Dictionary for element classifications.

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module. TIME STAMPS for vital signs and laboratory measurements are required. For the basic datasets, at minimum, record the average and lowest blood pressure over a given period. Vital signs should be recorded in relationship to the following temporal assessments:

1. Initial emergency department (ED) vital signs,
2. Final ED vital signs,
3. Admission vital signs and, at minimum, daily thereafter,
4. Any pre-intervention vital signs.

SETTING-SPECIFIC DOCUMENTATION: Pre-hospital setting - Documenting available pre-hospital vital signs is strongly encouraged. Intensive Care Unit (ICU) setting - In the ICU environment, recording blood pressure hourly is recommended, and especially when intracranial pressure (ICP) is monitored to permit determination of cerebral perfusion pressure (CPP), calculated as mean arterial blood pressure (MABP) - ICP (intermediate data set).

CEREBRAL PERFUSION PRESSURE: In participants with severe traumatic brain injury, routine calculation of the cerebral perfusion pressure on an hourly basis is recommended.

- Respiratory rate – The suggested range is 0-50 breaths per minute. Add date stamp for when assessed. Hypoxia, hypercapnia, and hypocapnia have all been associated with poor outcomes.
- Heart rate – Record heart rate from monitor or by counting pulse rate. The suggested range is 0-300. Add date stamp for when assessed. This measure is important because heart rate may be altered by trauma, and may indicate volume depletion, pain or stress. Higher heart rates have been found in participants that do not survive traumatic injuries. Bradycardia may be seen with elevated intracranial pressure.
- Blood pressure (systolic/diastolic) measurement – Record systolic and diastolic blood pressure from the blood pressure monitor or measure manually by sphygmomanometry with a time and date stamp. At minimum, the lowest daily blood pressure recording is required. The suggested range for measurements is 0-300 mmHg. When hourly values are documented, taking readings at a fixed time point is recommended, for example the last minute of the hour. Exclude values which may be

Vital Signs and Blood Gases CRF Module Instructions

influenced by artifacts. Because the injured brain is often not able to pressure autoregulate normally, adequate perfusion may be more dependent on perfusion pressure; lower blood pressure and low perfusion pressure can aggravate ischemic damage to the injured brain. Conversely high blood pressure may lead to increased intracranial pressure and carries an increased risk of neurogenic lung edema. Hypotensive episodes before and after admission adversely affect outcomes. Historically, blood pressure measurements may not have consistently been recorded in children – this practice is no longer supported and considered erroneous. All children should have frequent blood pressure assessment using an appropriately sized blood pressure cuff in line with afore mentioned recommendations. Optimal pediatric-specific systolic blood pressure following TBI should be targeted to the 75th and greater percentile for age as listed below:

- 28 days and younger > 70 mmHg
- 1–12 months > 84 mmHg
- 1–5 years > 90 mmHg
- 6 years and older > 100 mmHg
- Adults 110 mmHg and above
- Blood pressure measurement method – Choose one.
- Daily mean value of blood pressure – The suggested range is 0-300 mmHg.
- Mean arterial pressure (MAP) – The MAP is the pressure in the arteries in one cardiac cycle. Indicates how well the vital organs are perfused. $MAP = 2(DBP) + SBP / 3$. Normal range 70-100mm Hg.
- Pulse oximetry oxygen saturation – The suggested range is 0-100. Add date stamp for when assessed. Recommended for collection on admission and daily as required by protocol.
- Pulse oximetry daily minimal value of oxygen saturation – The suggested range is 0-100. Add date stamp for when assessed. Recommended for collection on admission and daily as required by protocol.
- Type of respiration – Choose one relevant to the time respiratory rate was measured. When recording respiratory rate, it is considered essential to link the rate to the type of ventilation (spontaneous or ventilated) at the same time.
- Respiratory support device – Choose all that apply. Recommend collection immediately upon arrival in the emergency department, prior to resuscitation therapy.
- Type of airway support – Choose all that apply.
- Type of circulation support – Choose all that apply.
- Body temperature – Response is measured in degrees Celsius with a time/date stamp for when assessed.
- Maximum daily body temperature – The suggested range is 32-120 degrees Fahrenheit and 0-50 degrees Celsius.
- Minimum daily body temperature – The suggested range is 32-120 degrees Fahrenheit and 0-50 degrees Celsius.
- Mean daily body temperature – The suggested range is 32-120 degrees Fahrenheit and 0-50 degrees Celsius.
- Temperature method – Choose one. If Other, specify is chosen, enter other temperature method.
- Partial pressure of oxygen in brain tissue – Capture in millimeters of mercury (mmHg).
- [Arterial/Venous] blood oxygen saturation – The suggested range is 0-100. Add date stamp for when assessed. Recommended for collection on admission and daily as required by protocol.
- Partial pressure of carbon dioxide in [arterial/venous] blood – The suggested range is 0-99 mmHg or 0-13.2 kPa. Recommended for collection on admission and daily as required by protocol.
- ~~• Mean measurement of the [arterial/venous] partial pressure of carbon dioxide – The suggested range is 0-99 mmHg or 0-13.2 kPa. Recommended for collection on admission and daily as required by protocol.~~
- Partial pressure of oxygen in [arterial/venous] blood – The suggested range is 0-650 mmHg or 0-86.5 kPa. Recommended for collection on admission and daily as required by protocol.
- [Arterial/Venous] blood pH value – The suggested range is 7.35-7.45.
- Blood gases pressure unit of measure – Choose one.

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