Summary of Core and Supplemental – Highly Recommended Recommendations: Sport-Related Concussion

Start-up Resource – NINDS Sport-Related Concussion CDE Recommendations

The National Institute of Neurological Disorders and Stroke (NINDS) and other Federal agencies and international organizations have the common mission of developing data standards for clinical research. Through the efforts of subject-specific working groups, topic-driven data elements have been created. The first set of Common Data Elements (CDEs) for Sport-Related Concussion was developed in 2017. The Core data elements to be used by an investigator when beginning a research study in this disease/disorder are listed in this resource document. All other recommendations are listed on the website and should be considered based on study type.

Each CDE or instrument could be classified according to the definitions below:

General Core: A data element that is required for all NINDS funded studies.

Disease Core: A data element that collects essential information applicable to any disease-specific study, including all therapeutic areas. The NINDS and its appointed working groups assign the disease "Core" classification based on the current clinical research best practices. In each case, the disease Core CDEs are a small subset of the available CDEs, where it is anticipated that investigators will need to collect the disease Core CDEs on any type of study. These are required for all disease-specific studies.

Disease Supplemental – Highly Recommended: A data element which is essential based on certain conditions or study types in clinical research studies. In most cases, these have been used and validated in the disease area. These data elements are strongly recommended for the specified disease condition, study type or design.

Disease Supplemental: A data element which is commonly collected in clinical research studies. Use depends upon the study design, the protocol, or the type of research involved. These are recommended, but not required, for studies.

Disease Exploratory: A data element that requires further validation but may fill current gaps in the CDEs and/or substitute for an existing CDE once validation is complete. Such data elements show great promise but require further validation before they are ready for prime-time use in clinical research studies. They are reasonable to use with the understanding that it has limited validation in the target group.

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National Institute of Health (NIH) Resources: *The NINDS also strongly encourages researchers to use these NIH developed materials for NINDS-sponsored research, when appropriate. Utilization of these resources will enable greater consistency for NINDS-sponsored research studies. These tools are free of charge.*	• **NIH Toolbox** • **Quality of Life in Neurological Disorders (Neuro-QOL)** • **Patient-Reported Outcomes Measurement Information System (PROMIS)**

Core CDEs for all NINDS Studies[1]:

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

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

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General Core for all Studies:

Investigators should review the FDA's "Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials" for the most up-to-date information about suicidal ideation and behavior. One scale that FDA suggests is the Columbia Suicide Severity Rating Scale (C-SSRS) (available at Columbia Suicide Severity Rating Scale).

Core Instruments for Sport-Related Concussion:

Acute timeframe (time of injury until 72 hours)

1. Balance Error Scoring System (BESS) (Modified)
2. Automated Neuropsychological Assessment Metrics (ANAM)
3. Axon Sports Computerized Cognitive Assessment Tool (CCAT)
4. Sport Concussion Assessment Tool (SCAT-3) or 5
5. Child Sport Concussion Assessment Tool (Child-SCAT)
6. CNS Vital Signs
7. Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT)
8. Post-concussion Symptom Inventory (PCSI)
9. Post Concussion Symptoms Scale (PCSS)
10. Standardized Assessment of Concussion (SAC)
11. The Rivermead Postconcussive Symptom Questionnaire (RPQ)

Subacute timeframe (after 72 hours to 3 months

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1. Automated Neuropsychological Assessment Metrics (ANAM)
2. Axon Sports Computerized Cognitive Assessment Tool (CCAT)
3. CNS Vital Signs
4. Health and Behavior Inventory (HBI)
5. Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT)
6. Post-concussion Symptom Inventory (PCSI)
7. Post Concussion Symptoms Scale (PCSS)
8. The Rivermead Postconcussive Symptom Questionnaire (RPQ)

Persistent/Chronic timeframe (3 months and greater post concussion)

1. Automated Neuropsychological Assessment Metrics (ANAM)
2. Axon Sports Computerized Cognitive Assessment Tool (CCAT)
3. CNS Vital Signs
4. Health and Behavior Inventory (HBI)
5. Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT)
6. Post-concussion Symptom Inventory (PCSI)
7. Post Concussion Symptoms Scale (PCSS)
8. The Rivermead Postconcussive Symptom Questionnaire (RPQ)

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Supplemental – Highly Recommended Instruments for Sport-Related Concussion:

Acute timeframe (time of injury until 72 hours)

1. Brief Symptom Inventory-18 (BSI-18)
2. Center for Epidemiologic Studies Depression Scale (CES-D)
3. Children's Orientation and Amnesia Test (COAT)
4. Controlled Oral Word Association Test (COWAT)
5. Health and Behavior Inventory (HBI)
6. Hopkins Verbal Learning Test - Revised (HVLT-R)
7. Trail Making Test (TMT)
8. Wechsler Adult Intelligence Scale (WAIS-IV)
9. Wechsler Intelligence Scale for Children (WISC-V)

Subacute timeframe (after 72 hours to 3 months)

1. Controlled Oral Word Association Test (COWAT)
2. Dizziness Handicap Inventory (DHI)
3. Hopkins Verbal Learning Test -Revised (HVLT-R)

4. Pediatric Quality of Life Inventory (PEDSQL)
5. Standardized Assessment of Concussion (SAC)
6. Trail Making Test (TMT)
7. VOMS (Brief Vestibular/Ocular Motor Screening Assessment)
8. Wechsler Adult Intelligence Scale (WAIS-IV)
9. Wechsler Intelligence Scale for Children (WISC-V)

Persistent/Chronic timeframe (3 months and greater post concussion)

1. Controlled Oral Word Association Test (COWAT)
2. Dizziness Handicap Inventory (DHI)
3. Dynamic Gait Index
4. Functional Gait Assessment
5. Hopkins Verbal Learning Test -Revised (HVLT-R)
6. Trail Making Test (TMT)
7. Wechsler Adult Intelligence Scale (WAIS-IV)
8. Wechsler Intelligence Scale for Children (WISC-V)

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For the complete list of NINDS CDE recommendations for Sport-Related Concussion, please see the NINDS CDE website.