

NINDS CDE Project Biomechanical Devices in TBI Head Accelerometry Subgroup

The Head Accelerometry subgroup developed recommendations for data collection of sub-concussive head accelerometry exposures, without any other clinical information. Therefore, a case is defined to be a period of time where some exposure was recorded. However, in case of a TBI with clinical information, this same data structure should be used. Data in the Head Kinematic Estimates Case Report Form (CRF), developed by this subgroup, should serve as a summary header file for data to be shared.

The subgroup drafted these recommendations by reviewing example case report forms submitted by subgroup members and selecting and classifying them. Further instructions, permissible values and units were added as needed.

These recommendations are specific to inertial injury TBI, which assumes the skull acts as a rigid body and the brain is injured due to its own mass lagging behind the skull. If the brain is instead injured by local deformation of the skull, or crushing without inertial acceleration, these inertial sensors may not be appropriate.

The subgroup was asked if there were any issues unique to biomechanical devices used in TBI (e.g., any issues encountered when developing the CDE standards or unique concerns about biomechanical devices data collection) and the following issues were noted within this subgroup:

- Field vs. lab data collection
- Is data provided by manufacturer?
- Do “typical” researchers have skills /expertise to make measurement?
- Is it cost-prohibitive?

For future iterations of the CDEs, the following unmet needs were identified via the CDE development process for biomechanical devices used in TBI:

- Repository for shared data
- Methods for automatically populating header file and uploading
- Industry adoption of NINDS CDEs
- Validation standards
 - Laboratory
 - Human
 - For different applications
- Sensor standards
- Device safety standards
- Regulatory approvals for consumer devices. Distinction between research and consumer grade devices?
- Biostatistical standards