







INSTRUCTIONS Preclinical Traumatic Brain Injury (Preclinical TBI) Common Data Element (CDE) Public Review Package Overview

The Preclinical Traumatic Brain Injury (Preclinical TBI) Working Group and the NIH/NINDS/DOD CDE Team have released a draft version (Pre-release Version 0.1) of the Preclinical TBI CDEs for public review. We are in the process of finalizing these documents and would like to urge you to help by contributing your expertise during this public review period. Information about the NINDS CDE project can be found at https://commondataelements.ninds.nih.gov.

This Pre-release Version 0.1 Preclinical TBI CDE Public Review 2 package contains the following documents:

- Instructions (current document Instructions on reviewing and submitting comments)
- CDE spreadsheet guide (Description for the CDE spreadsheet columns; please review columns A, B, C, E, F, G, H, I, J, K, L, M, O, P, Q, R)
- Materials prepared by the working group
 - i. Quick start guide (Reference document for the tests/instruments)
 - ii. Common Data Element (CDE) spreadsheets per instrument/test (CDE sets are available as excel spreadsheets which include the CDEs identified and defined by the Preclinical TBI Working Groups. The CDE sets can be used as the building blocks for study data collection forms.)
- Comments spreadsheet that can be filled out and sent to PreclinicalCDE@nih.gov

The Common Data Element Spreadsheet (CDEs) modules include the Common Data Elements (CDEs) identified and defined by the Preclinical TBI Working Group. These can be used as the building blocks for study data collection forms. Each CRF will have a corresponding data dictionary to define the CDEs on the form. The Quick Start Guide includes a description, location, and impairment that can be researched using the instruments/tests as recommended for Preclinical TBI's.

Please send all comments to PreclinicalCDE@nih.gov by February 15, 2018.

After this open comment period, the Preclinical TBI Working Group will review and revise the recommendations. Version 1.0 of the Preclinical TBI recommendations will be posted by **April 30, 2018**.