

For Researchers

TRACK-TBI U01 Protocols

Follow the links below to download protocols and study related documents.

[TRACKTBI U01 Clinical Protocol V14-July 6 2016 Current.pdf](#) [1]

[Clinical Protocol Change Log V14 July 6 2016-Current.pdf](#) [2]

[Outcome Assessment SOP.pdf](#) [3]

[V2 TRACK-TBI MRI Manual_01OCTOBER2015.pdf](#) [4]

[V4 TRACK-TBI Biospecimens SOP 5 MAY 2016.pdf](#) [5]

TRACK-TBI Pilot Protocols and Statistics

[TRACK Pilot SOP FINAL.pdf](#) [6]

[TRACK-TBI DataDictionary Excel May 2012.xls](#) [7]

[TRACK-TBI Pilot CRF.pdf](#) [8]

[TRACK-TBI Implementation Manuscript.pdf](#) [9]

[Summary_Statistics_v2.pdf](#) [10]

[TRACKTBI-PILOT_variable list.xlsx](#) [11]

NINDS Common Data Elements

Streamline Your Neuroscience Clinical Research using content standards that enable clinical investigators to systematically collect, analyze, and share data across the research community. The NINDS strongly encourages researchers who receive funding from the Institute to ensure their data collection is compatible with these common data elements (CDEs). [Learn more about the CDE Project](#) [12].

FITBIR: Federal Interagency Traumatic Brain Injury

The Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system was

developed to share data across the entire TBI research field and to facilitate collaboration between laboratories, as well as interconnectivity with other informatics platforms. Sharing data, methodologies, and associated tools, rather than summaries or interpretations of this information, can accelerate research progress by allowing re-analysis of data, as well as re-aggregation, integration, and rigorous comparison with other data, tools, and methods. This community-wide sharing requires common data definitions and standards, as well as comprehensive and coherent informatics approaches. Click [here](#) [13] to learn more about FITBIR.

CENTER-TBI

CENTER-TBI is a large European project that aims to improve the care for patients with Traumatic Brain Injury (TBI). It forms part of the larger global initiative InTBIR: International Initiative for Traumatic Brain Injury Research with projects currently ongoing in Europe, the US and Canada. The Center-TBI website can be found [here](#) [14].

BEST (Biomarkers, EndpointS, and other Tools) Resource

Effective, unambiguous communication is essential for efficient translation of promising scientific discoveries into approved medical products. Unclear definitions and inconsistent use of key terms can hinder the evaluation and interpretation of scientific evidence and may pose significant obstacles to medical product development programs. In the spring of 2015 the FDA-NIH Joint Leadership Council identified the harmonization of terms used in translational science and medical product development as a priority need, with a focus on terms related to study endpoints and biomarkers. Working together with the goals of improving communication, aligning expectations, and improving scientific understanding, the two agencies developed the BEST (Biomarkers, EndpointS, and other Tools) Resource. The BEST glossary aims to capture distinctions between biomarkers and clinical assessments and to describe their distinct roles in biomedical research, clinical practice, and medical product development. To access the glossary, click [here](#) [15].

[UCSF Main Site](#)

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Source URL: <http://tracktbi.ucsf.edu/researchers>

Links:

- [1] <https://tracktbi.ucsf.edu/sites/tracktbi.ucsf.edu/files/Final%20TRACKTBI%20U01%20Clinical%20Protocol%20V14-July%206%202016%20Current.pdf>
- [2] <https://tracktbi.ucsf.edu/sites/tracktbi.ucsf.edu/files/Clinical%20Protocol%20Change%20Log%20V14%20%20July%206%202016%20Current.pdf>
- [3] <https://tracktbi.ucsf.edu/sites/tracktbi.ucsf.edu/files/Outcome%20Assessment%20SOP.pdf>
- [4] https://tracktbi.ucsf.edu/sites/tracktbi.ucsf.edu/files/V2_TRACK-TBI_MRI_Manual_01OCTOBER2015.pdf
- [5] <https://tracktbi.ucsf.edu/sites/tracktbi.ucsf.edu/files/V4%20TRACK-TBI%20Biospecimens%20SOP%205%20MAY%202016.pdf>
- [6] <https://tracktbi.ucsf.edu/sites/tracktbi.ucsf.edu/files/TRACK%20Pilot%20SOP%20FINAL.pdf>
- [7] <https://tracktbi.ucsf.edu/sites/tracktbi.ucsf.edu/files/TRACK-TBI%20Pilot%20SOP%20FINAL.pdf>

TBI%20DataDictionary%20Excel%20May%202012.xls

[8] <https://tracktbi.ucsf.edu/sites/tracktbi.ucsf.edu/files/TRACK-TBI%20Pilot%20CRF.pdf>

[9] <https://tracktbi.ucsf.edu/sites/tracktbi.ucsf.edu/files/TRACK-TBI%20Implementation%20Manuscript.pdf>

[10] https://tracktbi.ucsf.edu/sites/tracktbi.ucsf.edu/files/Summary_Statistics_v2.pdf

[11] https://tracktbi.ucsf.edu/sites/tracktbi.ucsf.edu/files/TRACKTBI-PILOT_variable%20list.xlsx

[12] <http://www.commondataelements.ninds.nih.gov/ProjReview.aspx>

[13] <https://fitbir.nih.gov/>

[14] <https://www.center-tbi.eu/>

[15] <http://www.ncbi.nlm.nih.gov/books/NBK338448/>