SOP manual for data access and publication requests

This SOP manual for data access and publication requests addresses harmonized procedures for the data access requests and publication of data collected under the protocol entitled: “Collaborative European NeuroTrauma effectiveness Research in TBI”, Acronym “CENTER-TBI”

(HEALTH.2013.2.2.1-1: Grant agreement 602150; ClinicalTrials.gov Identifier: NCT02210221).

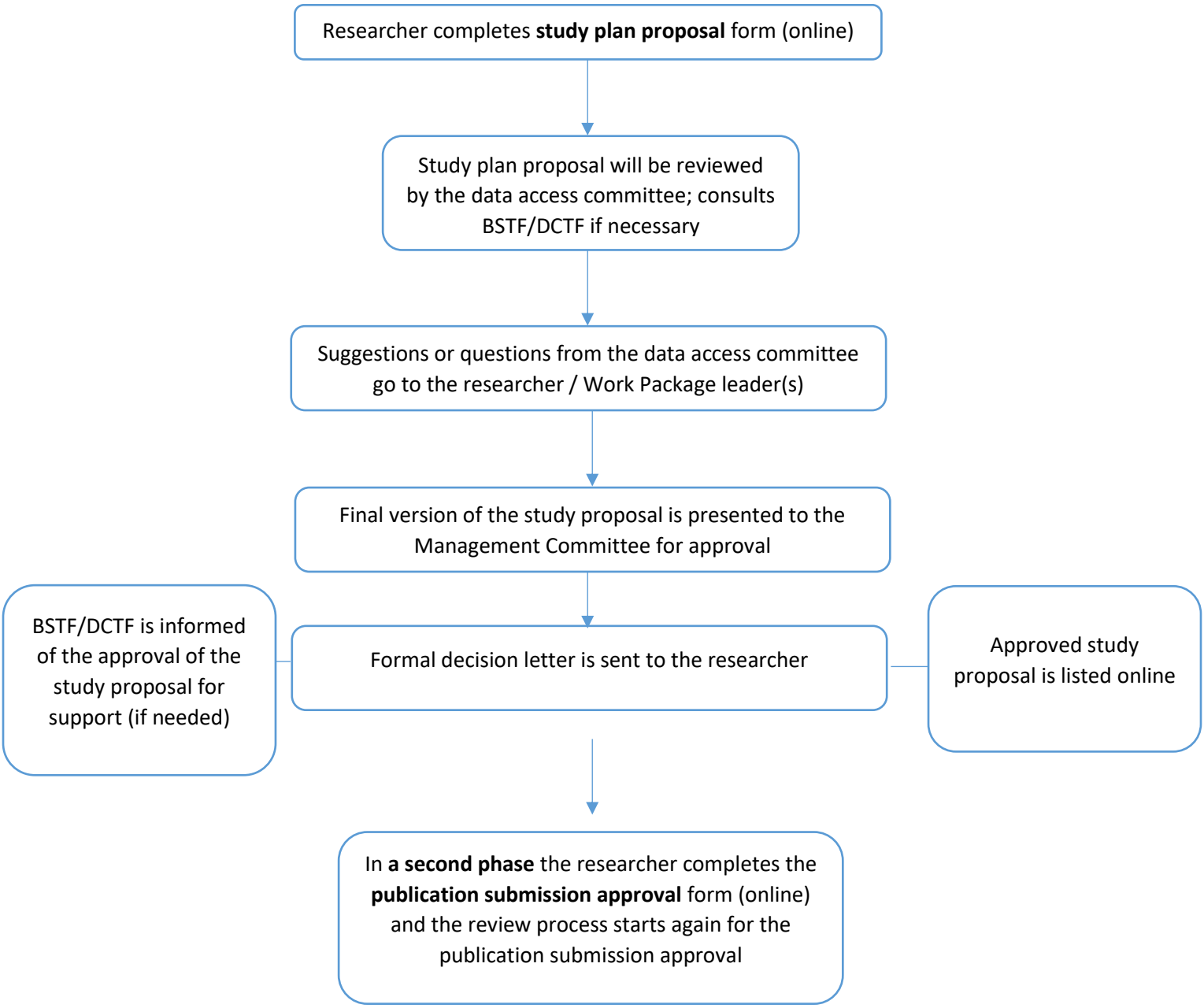
This guideline may be subject to refinement as ongoing experience and new insights from this study may necessitate periodic modification by consensus of the Management Committee.

Table of contents

Abbreviations

BSTF	Bioinformatics and Statistical Task Force
DAC	Data Access Committee
DCTF	Data Curation Task Force
DoW	Description of Work
EC	European Commission
MC	Management Committee
WP	Work Package

Flow chart



Members Data Access Committee: Andrew Maas, David Menon, Giuseppe Citerio, Ewout Steyerberg

1.0 Data access request (study plan proposal)

All researchers (participants, investigators or external) should complete a study plan proposal through the online form of CENTER-TBI (see appendix 1).

Participants (Work Package members) should prioritize the research questions as described in the work packages to the EC. This is important as these are official milestones that need to be reported to the EC at designated times.

The study plan proposal will be reviewed by the Data Access Committee for scientific and managerial aspects. Members of the Data Access Committee (DAC) are Andrew Maas, David Menon, Giuseppe Citerio, Ewout Steyerberg. The DAC will liaise with the DCTF (Data Curation Task Force) and/or BSTF (Bioinformatics and Statistical Task Force) if input on data and analysis issues is requested by the applicant or considered desirable by DAC.

The DAC will feedback suggestions or questions to the researcher as appropriate, will discuss the study plans with the concerned WP leaders if applicable, and will present the final study plan to the Management Committee (MC).

If a study plan concerns a research question that is already being studied within the framework of CENTER-TBI, the concerned researchers or research groups will be directed towards collaboration on the same research question.

A decision letter (with motivation) will be sent to the researcher. All approved study plans will be listed on the CENTER-TBI website, so will be accessible to the CENTER-TBI research community. For all approved study plans not pre-specified in the DoW a Data use agreement will need to be signed.

The Data Curation Task Force (DCTF) and Bioinformatics and Statistical Task Force (BSTF) will be informed of the study plan and their support will be requested if necessary.

2.0 Publication request (Publication Submission Approval)

Three types of manuscripts are distinguished

a) Manuscripts reporting the major objectives of the trial (i.e., the major results of the collaboration).

b) Manuscripts referring to pre-specified hypotheses and ancillary analyses specified in the Work Packages (WP) description of work (DoW). These publications will be the responsibility of the relevant Beneficiaries, and the WP leader will ensure adequate coordination between Parties.

c) Manuscripts in which ancillary data and research questions, unrelated to the primary study hypotheses or in WPs, are analyzed, sometimes on only a subset of study data. Research questions that are not specified in the DoW can be addressed following notification to and approval by the Management Committee in accordance with the procedure set forth in the Publication and Authorship Guideline CENTER-TBI (see annex 3).

Manuscripts listed under a) are led by the Management Committee (MC).

For manuscripts listed under b) and c) the researchers should submit a Study proposal plan (see 1.0) and in a later phase, once the pre-final manuscript is ready, a Publication Submission Approval form (see annex 2) in follow up of the submitted study proposal plan.

For approved study plans, the researcher performs the study and writes the manuscript within the timeframe indicated in the Data Access Request form. A draft manuscript is sent to the authors and contributors for feedback and eventually final approval. After final approval by the authors, the pre-final (draft) manuscript is submitted to the DAC 14 days prior to submission.

Publication Submission Approvals will be reviewed by the Data Access Committee. Members of the Data Access Committee (DAC) are Andrew Maas, David Menon, Giuseppe Citerio, Ewout Steyerberg. The DAC will liaise with the DCTF (Data Curation Task Force) and/or BSTF (Bioinformatics and Statistical Task Force) if input on data and analysis issues is required.

The DAC will feedback suggestions or questions to the researcher as seemed appropriate, will discuss the publication submission approval with the concerned WP leaders if applicable, and will present the final publication submission approval to the Management Committee (MC).

A decision letter (with motivation) will be sent to the applicant.

Upon agreement, the manuscript is submitted to the journal. The authors inform the DAC when a manuscript is accepted for publication. All accepted manuscripts are listed on the CENTER-TBI website.

3.0 Data Access

The CENTER-TBI database is accessible through 2 platforms, Neurobot and Mica/Opal.

Access will be granted after approval of a Study Plan proposal, submitted through the online system (see 1.0. Data access request).

Neurobot:
Neurobot is a data access tool developed by INCF in close collaboration with the CENTER-TBI Data Curation Task Force. It meets the needs of CENTER-TBI researchers to easily find the study variables and export them for further analysis. In addition to the Clinical data, the associated imaging and ICU data, biomarkers and outcome data are available through Neurobot. Links are provided to large data files such as imaging and high resolution ICU data, and they are combined with the clinical data of the individual patients based on the Global Unique Personal Identifier (GUPI).

The downloaded data from Neurobot in csv format work best with Microsoft office and Google spreadsheet. Problems may occur when using Libre Office.

Mica/Opal:
Mica and Opal are part of the Obiba open source software suite.

Mica is an online data portal that includes the study catalogue and a searchable variable dictionary giving insight into the CENTER-TBI dataset. It also provides additional information on the study goals, design and participants.

Opal is the data warehouse where you can view your dataset and export & download the data, or connect your R session to the Opal API. Because of its integration with R, complex statistical analysis and reports can be performed within Opal as well.

External researchers applying for access to the CENTER-TBI dataset, should follow the following work flow:

- Check available variables in MICA
- Submit a study proposal with in attachment the zip file with variables you request from MICA (see MICA user manual: Data access and shopping cart))

Appendix 1 – Study plan proposal form – to complete online!

Date:

Name and Scope of Project	
Name of Project	
Is this project part of a pre-specified CENTER-TBI WP? (indicate the WP, if applicable)	

Lead Researcher—Name and Affiliations	
First Name	
Family Name	
Job Title/Designation	
Organization Affiliation	
Country of Residence	
Email Address	
Telephone Number	
Other Researchers—Name and Qualifications	
Names, Titles, and Experience of Any Additional Researchers Involved	

Project Overview	
Start Date	
Expected Completion Date	
Background	
Study objective(s)	
Hypothesis	
Methods	
Expected results	
Aim of the project (specify if different from publication on a peer reviewed journal)	
CENTER-TBI Work Package the project may relate to	

Type of Data Requested, based on data dictionary	
Data source (Core study, Registry, Imaging repository, Biomarker repository, DNA repository, and/or High resolution ICU data)	
Type of data required (list of the field required)	
Statement of storage method by which access to data will be limited to research team members only	

Data Curation Task Force (DCTF) support required (specify request / name)	
Bioinformatics and Statistical Task Force (BSTF) support required (specify request / name)	

Terms and Conditions for Use of CENTER-TBI Data

The researcher(s) must agree to the following terms and conditions with regard to access and use of CENTER-TBI data.

- Use the data only for the purposes described in this request.
- Keep all the research information shared with confidential by not discussing or sharing the research information in any form or format with anyone other than the CENTER-TBI researcher(s).
- Follow the most recent CENTER-TBI publication and authorship guideline, approved by the General Assembly, in any stage of the project (from data access till publication and dissemination),
- Meet the requirements of the institution's Ethical Review Board or corresponding committee.
- Keep all research information in any form or format (e.g., HD, computers) secure and accessible only by research team members.
- Share scripts for data management and statistical analysis among CENTER-TBI researchers.
- Acknowledge CENTER-TBI collaboration and funding in all research product as: "The research leading to these results was supported by the European Union's Seventh Framework Program (*FP7/2007-2013*) under *grant agreement* n° 602150 (CENTER-TBI)." – see also appendix 5.

Appendix 2 – Publication Submission Approval form – to complete online!

Date:

Title and Scope of Publication	
Study plan was approved	Yes / No
Publication title	
Is this project part of a pre-specified CENTER-TBI WP? (indicate the WP, if applicable)	

First Author—Name and Affiliations	
First Name	
Family Name	
Job Title/Designation	
Organization Affiliation	
Country of Residence	
Email Address	
Telephone Number	
Authors and collaborators—Name and Qualifications	
Proposed authors	
Proposed collaborators (may be: and the Center TBI collaborators)	

Publication Overview	
Background	
Study objective(s)	
Hypothesis	
Statistical analysis plan	
Expected results	
Target journal(s)	
CENTER-TBI Work Package the project may relate to	

Uploaded pre-final manuscript

Checklist to submit with the pre-final version	
Study plan was approved (linked to section 1)	Yes / No
Is "CENTER-TBI" recognizable in the title/subtitle/authors' list? *	Yes / No
Appropriate funding sources mentioned? *	Yes / No
Appropriate lists of authors and collaborators reflecting contribution made to the manuscript? *	Yes / No
Appropriate Ethics statement included? *	Yes / No

Terms and Conditions for Use of CENTER-TBI Data

The researcher(s) must agree to the following terms and conditions with regard to access and use of CENTER-TBI data.

- Use the data only for the purposes described in this request.
- Keep all the research information shared with confidential by not discussing or sharing the research information in any form or format with anyone other than the CENTER-TBI researcher(s).
- Follow the most recent CENTER-TBI publication and authorship guideline, approved by the General Assembly, in any stage of the project (from data access till publication and dissemination),
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- Keep all research information in any form or format (e.g., HD, computers) secure and accessible only by research team members.
- Share scripts for data management and statistical analysis among CENTER-TBI researchers.
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Appendix 3 - Publication and Authorship Guideline CENTER-TBI

These Publication and Authorship Guidelines have been approved by the General Assembly at its meeting of Sept 11-12, 2017 in Antwerp.

The overall aim of the Publication and Authorship Guideline is to stimulate, harmonize and streamline high-quality scientific output from the CENTER-TBI project.

Specific goals:

- Maximize the quality of scientific output, including procedures for bioinformatics and statistical support,
- Increase efficiency and avoid duplication of research with CENTER-TBI data,
- Harmonize and streamline structure and format of publications,
- Define authorship criteria, fostering the involvement of different entities participating to the Consortium in the production of scientific outputs,
- Maintain transparency towards CENTER-TBI investigators, CENTER-TBI collaborators, and external data requests.
- Ensure identification of the CENTER-TBI consortium as the publication source where appropriate.

This guideline addresses three types of manuscripts:

- Manuscripts reporting the major objectives of the trial (i.e., the major results of the collaboration).
- Manuscripts referring to pre-specified hypotheses and ancillary analyses specified in the Work Packages (WP) description of work (DoW). These publications will be the responsibility of the relevant Beneficiaries, and the WP leader will ensure adequate coordination between Parties.
- Manuscripts in which ancillary data and research questions, unrelated to the primary study hypotheses or in WPs, are analysed, sometimes on only a subset of study data. Research questions that are not specified in the DoW can be addressed following notification to and approval by the Management Committee in accordance with the procedure set forth below.

General principles

Primary Authorship, denoted as those on the first line(s) of the authorship attribution in a journal and in indexing services, should be based on appropriate effort as defined in the guidelines published by the International Committee of Medical Journal Editors (ICMJE, http://www.icmje.org/roles_a.html). According to these guidelines, primary authors should meet all four of the following criteria:

a. Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; AND

b. Drafting the work or revising it critically for important intellectual content; AND

c. Final approval of the version to be published; AND

d. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Authorship credits are granted for primary authors who are involved in drafting and revision of the manuscript.

Where manuscripts are reporting the major objectives of the collaboration, CENTER-TBI Participants and Investigators involved in the work (including data collection) should also receive academic credits.

For this reason, all publications regarding the main objectives and those based on broad collaborative efforts and on CENTER-TBI data should include a group designation in the author list as "and the CENTER-TBI Participants and Investigators". The group members will be listed in alphabetic order at the end of the manuscript.

Including the CENTER-TBI Study Investigators is a recognition of the academic effort involved in high quality data collection and should allow for all members (i.e. 2 clinical researchers per site) to be indexed in PubMed.

Scientific participants who are not on the primary author list of the manuscript can also be recognised in this group.

According to the current ICMJE criteria, group members will in general be considered as "Contributors", and as such qualify for academic credits. A list of "CENTER-TBI Study Investigators" including 2 clinical researchers per site (66 centres) will be maintained by the CENTER-TBI Coordinating centre. The Management Committee is committed to oversee procedures for group designation.

CENTER-TBI Data collected by a party under the project can be used by that party in any other research that is not part of the project. Analysis and reporting of CENTER-TBI data obtained by a single party or a single third party are not allowed prior to completion of the full analysis of the CENTER-TBI Database, unless it forms part of an ongoing project.

Study Plans and Proposal for Manuscripts

Manuscripts in which ancillary data and research questions, unrelated to the primary study hypotheses or in WPs, are explored, are strongly encouraged and may be initiated by any participating CENTER-TBI investigator or external collaborator.

The Management Committee will consider requests from unrelated third parties for access to study data for research and publication purposes prior to the data becoming available publically.

All study proposals and publication submission approvals - both from within CENTER-TBI and from external collaborators - should be submitted to the Data Access Committee/Management Committee. All eligible proposals will be discussed and reviewed, either during Management Committee meetings, or via email within 14 days from the submission. Approval of new study plans will be determined by simple majority, and – for external requests – be dependent on signing a data use agreement (https://www.center-tbi.eu/publications/datasharing). In order to optimise the data usage, the Management Committee will provide feedback on the research questions and scientific approach, also on those that have already been articulated in the grant.

The submitted proposals and advice of the Data Access Committee/Management Committee will be recorded in the minutes of the periodic TCs.

First authors are requested to submit results to be included in the primary manuscript to the Management Committee at an early stage for review and feedback, at which time they can also request support and advice from the Data Curation Task Force (DCTF) and/or the Bioinformatics and Statistical Task Force (BSTF).

Consultations with the DCTF and BSTF are encouraged. The DCTF will provide advice on selection and extraction of data variables. The BSTF is a central facility as defined in WP20, task 3, to provide advice and support with regard to statistical aspects and neuroinformatics analysis. Clinical site data managers, statisticians, epidemiologists, and clinical researchers are encouraged to participate in these consultations, which should take place before or after proposal submission to the Management Committee.

Proposals for manuscripts approval can be submitted using an online template form to the Management Committee.

After acceptance by the CENTER-TBI Management Committee, proposals will be posted on the CENTER-TBI Portal. Interested researchers from the CENTER-TBI community can contact the primary author for further information. Each study proposal will identify a primary author/writing group leader, who will be responsible for assigning tasks to members of the writing group. It is expected that primary authors will delegate writing responsibilities early enough so that all members of the writing group are given the opportunity to contribute substantively. The primary author will have responsibility for ensuring that authorship order has been discussed and confirmed by co-authors. If there is a disagreement among the potential co-authors, the Management Committee will arbitrate, and if unsuccessful determine inclusion of an author and/or order.

Preparing for manuscript submission

Two weeks prior to planned submission to a journal, a complete pre-final draft should be circulated to the Management Committee for review and comment (through the online form).

The corresponding author has to obtain a written permission from all authors/acknowledged individuals, and to ensure appropriate listing of the group designation in the manuscript. In general, group members are only entitled to listing in PubMed if they have completed relevant Conflict of Interest and Copyright forms prior to publication of the manuscript. It is noted, however, that journal policies may vary.

Support of the CENTER-TBI project needs to be always mentioned with reference to the European Union FP 7th Framework program (grant 602150). In some circumstances, additional funding may need to be mentioned as the Hannelore Kohl Foundation (Germany) and the non-profit organization One Mind (see appendix 5).

Publication

The first author is responsible for notifying the Coordinating centre, who is responsible for informing Management Committee, of all accepted manuscripts, abstracts, and oral and poster presentations,

as well as the journal, date of publication, page number(s) and other information necessary to reference the publication/presentation.

The first author is responsible for checking if the members of group authorship are picked up by PubMed. Recognizing that there may be delays of up to 6 months before listings in PubMed are up-to-date, they will perform all efforts to remedy any deficiencies.

The CENTER-TBI Administrative Core will maintain a central list of all accepted abstracts, presentations and publications relating to CENTER-TBI, which will be posted on the CENTER-TBI Web site.

Appendix 4 – Checklist to submit with the pre-final version of a proposed CENTER-TBI publication to the Management Committee

Background:

CENTER-TBI is a large and complex project, involving many research groups who are collaboratively working on the Project. The Management Committee would like to ensure transparency and consistency in reporting. Version 1.0 of Neurobot was released on November 1, 2018, but we anticipate updates in the future in response to feedback received from researchers. As a consequence, some inconsistencies in numbers may occur when analyses are performed on different versions. We therefore require specification of the version used and uploading of scripts so that analyses are documented and may be repeated.

To ensure these aims, we kindly request you to provide the information below when submitting your draft publication to the Management Committee. We will perform all efforts to complete the internal review in a timely fashion, and hope you may benefit from our feedback.

Title of manuscript:

First authors:

Collaborators:

Acknowledgements:

Checklist to submit with the pre-final version	
Study plan was approved (linked to section 1)	Yes / No
Is "CENTER-TBI" recognizable in the title/subtitle/authors' list? *	Yes / No
Appropriate funding sources mentioned? *	Yes / No
Appropriate lists of authors and collaborators reflecting contribution made to the manuscript? *	Yes / No
Appropriate Ethics statement included? *	Yes / No

Appendix 5 – Acknowledgements

Statements and acknowledgements to be used for CENTER-TBI manuscripts

Funding sources statement:

Data used in preparation of this manuscript were obtained in the context of CENTER-TBI, a large collaborative project with the support of the European Union 7th Framework program (EC grant 602150). Additional funding was obtained from the Hannelore Kohl Stiftung (Germany), from OneMind (USA) and from Integra LifeSciences Corporation (USA).

Ethical approval statement:

The CENTER-TBI study (EC grant 602150) has been conducted in accordance with all relevant laws of the EU if directly applicable or of direct effect and all relevant laws of the country where the Recruiting sites were located, including but not limited to, the relevant privacy and data protection laws and regulations (the "Privacy Law"), the relevant laws and regulations on the use of human materials, and all relevant guidance relating to clinical studies from time to time in force including, but not limited to, the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) ("ICH GCP") and the World Medical Association Declaration of Helsinki entitled "Ethical Principles for Medical Research Involving Human Subjects". Informed Consent by the patients and/or the legal representative/next of kin was obtained, accordingly to the local legislations, for all patients recruited in the Core Dataset of CENTER-TBI and documented in the e-CRF.

Ethical approval was obtained for each recruiting site. The list of sites, Ethical Committees, approval numbers and approval dates can be found on the website:
https://www.center-tbi.eu/project/ethical-approval

Methodology statement:

Data for the CENTER-TBI study has been collected through the Quesgen e-CRF (Quesgen Systems Inc, USA), hosted on the INCF platform and extracted via the INCF Neurobot tool (INCF, Sweden).

Version [xxx] of the CENTER-TBI dataset was used in this manuscript.

(if applicable):

For the Imaging repository, image data collection has been facilitated and hosted on the icometrix platform (icometrix, Leuven)

(if applicable):

For patient monitoring and data collection in the High-Resolution repository, the ICM+ platform (University of Cambridge, UK) and/or Moberg Neuromonitoring system (Moberg Research Inc., USA) were used.