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).

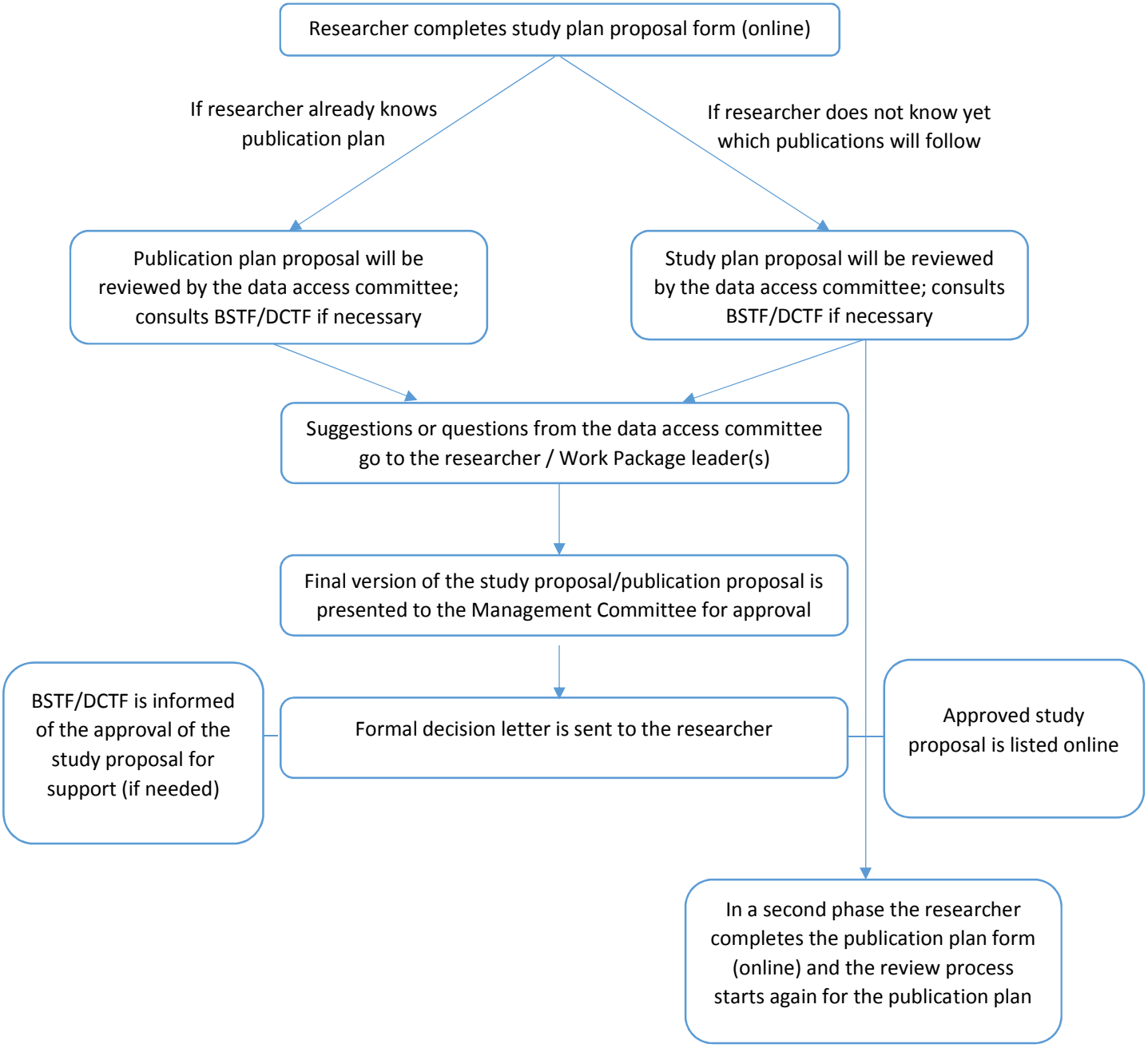
This guideline may be subject to refinement as ongoing experience and new insights from this study may necessitate periodic modification by consensus of the Management Committee.

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), if the researcher does not know yet which publications will follow.

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.

Researchers are encouraged to complete the publication plan (see appendix 2) online together with the study plan proposal. If a publication plan is not yet finalized, the plan can be submitted in a later phase.

The study plan proposals (and publication plan proposals) 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

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 the publication plan form (see annex 2), either together with the study proposal plan (see 1.0 en annex 1) or in a later phase in follow up of a submitted study proposal plan.

Publication plan proposals will be reviewed by the Data Access Committee for scientific and statistical review. 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 plans with the concerned WP leaders if applicable, and will present the final publication plan to the Management Committee (MC).

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

For approved publication 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 (draft) manuscript is submitted to the DAC 14 days prior to submission.

The DAC will feedback suggestions to the researcher as seemed appropriate and submit the manuscript to the MC for approval. The MC responds within 14 days.

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.

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.

1. Use the data only for the purposes described in this request.
2. 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).
3. 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),
4. Meet the requirements of the institution's Ethical Review Board or corresponding committee.
5. Keep all research information in any form or format (e.g., HD, computers) secure and accessible only by research team members.
6. Share scripts for data management and statistical analysis among CENTER-TBI researchers.
7. 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 Programme (*FP7/2007-2013*) under *grant agreement* n° 602150 (CENTER-TBI)."

Appendix 2 – Publication plan proposal form – to complete online!

Date:

Name and Scope of Project	
Title of publication	
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	
Authors and collaborators—Name and Qualifications	
Proposed authors	
Proposed collaborators (may be: and the Center TBI collaborators)	

Project Overview	
Start Date	
Expected Completion Date	
Background	
Study objective(s)	
Hypothesis	
Statistical analysis plan	
Expected results	
Target journal(s)	
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.

1. Use the data only for the purposes described in this request.
2. 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).
3. 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),
4. Meet the requirements of the institution's Ethical Review Board or corresponding committee.
5. Keep all research information in any form or format (e.g., HD, computers) secure and accessible only by research team members.
6. Share scripts for data management and statistical analysis among CENTER-TBI researchers.
7. 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 Programme (*FP7/2007-2013*) under *grant agreement* n° 602150 (CENTER-TBI)."

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:

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 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

1. 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.

2. Authorship credits are granted for primary authors who are involved in drafting and revision of the manuscript.
3. 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.
4. 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.
5. 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.
6. Scientific participants who are not on the primary author list of the manuscript can also be recognised in this group.
7. 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.
8. 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

9. 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.
10. 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.
11. All study proposals and plans for publication - 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.
12. The submitted proposals and advice of the Data Access Committee/Management Committee will be recorded in the minutes of the periodic TCs.
13. 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).
14. 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.

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

17. Two weeks prior to planned submission to a journal, a complete draft should be circulated to the Management Committee for review and comment. If no answer is received in two weeks, a positive response is assumed.
18. 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.
19. 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.

Publication

20. 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.
21. 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.
22. 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.