TRACK-TBI

Transforming Research and Clinical Knowledge in Traumatic Brain Injury

International Traumatic Brain Injury Research Initiative

Research Collaboration Policy

May 2, 2022

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TRACK-TBI Research Collaboration Policy

1. OBJECTIVES

The objective of the Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI) *Research Collaboration Policy* is to establish a framework to support the conduct of collaborative research projects involving the TRACK-TBI Investigators, the TRACK-TBI Dataset, and external parties.

1.1 TRACK-TBI STUDY DESCRIPTION

The TRACK-TBI study will directly impact public health by creating a Dataset of integrated clinical, imaging, proteomic, genomic, and outcome biomarkers, which will permit more precise TBI diagnosis, prognosis, and treatment, and which will accelerate the validation and regulatory readiness of candidate clinical outcome assessments (COAs), biomarkers, and devices. This research will: 1) permit more accurate disease/condition diagnosis, 2) identify patient subpopulations likely to benefit from therapy/intervention, and 3) provide refined outcome assessments to confirm efficacy.

Detailed data from subjects across the TBI injury spectrum, along with CT/MRI imaging, blood biospecimens, and outcomes measures, will be curated and analyzed, permitting the identification/validation of COAs and biomarkers, and identification of structural abnormalities that may be predictive of outcomes, making strides toward a new taxonomy for TBI. The knowledge network of databases and imaging and biospecimen repositories will create a high quality, legacy database for current and future generations of international researchers.

1.2 TRACK-TBI LEADERSHIP (EXECUTIVE and STEERING COMMITTEES)

TRACK-TBI is a large and complex project. Its institutional and public-private partnership is comprised of numerous study sites, managed through 7 Cores (Administrative, Biospecimen, Biostatistical and Comparative Effectiveness Research, Clinical, Informatics, Neuroimaging, Outcomes) totaling nearly 50 collaborating institutions, corporations, and philanthropies. Governance is implemented by the Executive Committee, consisting of leaders of the Cores. The Executive Committee receives input from a Steering Committee, consultants, and participating organizations as to strategic research participation and planning, and dissemination of TRACK-TBI scientific findings.

Oversight of Research Collaborations will be performed by the TRACK-TBI Executive Committee, which meets bi-weekly with few exceptions, and the Steering Committee. Submitted Research Collaboration Request forms will be screened, reviewed, and approved/rejected by the by the Executive Committee.

TRACK-TBI Executive Committee		
Name	Role	Institution
Geoffrey Manley, MD, PhD	Contact PI, Admin Core Leader	UCSF
Ramon Diaz-Arrastia, MD	PI, Emerging Tech Core Leader	University of Pennsylvania
Joseph Giacino, PhD	PI, Clinical/Rehab Core Leader	Spaulding Rehabilitation Center
Pratik Mukherjee, MD PhD	PI, Neuroimaging Core Leader	UCSF
David Okonkwo, MD PhD	PI, Clinical/Rehab Core Leader	University of Pittsburgh
Murray Stein, MD MPH	PI, Outcomes Core Co-Lead	University of California, San Diego
Nancy Temkin, PhD	PI, Biostatistics Core Leader	University of Washington
Claudia Robertson	PI, Clinical/Rehab Core Leader	Baylor College of Medicine

TRACK-TBI Steering Committee (Subject to Change)		
Name	Role	Institution
Geoffrey Manley, MD PhD	Contact PI, Admin Core Leader	UCSF
Ann-Christine Duhaime, MD	Clinical Core Co-Leader (Pediatrics), Site Leader	Harvard Medical School
C. Dirk Keene, MD PhD	Pathology Core Leader	University of Washington
Laura Ngwenya, MD PhD	Study Site Leader	University of Cincinnati
Neeraj Badjatia, MD	Study Site Leader	University of Maryland
Randall Chesnut, MD	Study Site Leader	University of Washington
Gillian Hotz, PhD	Study Site Leader	University of Miami
Christopher Madden, MD	Study Site Leader	UT Southwestern
Randall Merchant, PhD	Study Site Leader	Virginia Commonwealth University
Alex Valadka, MD	Study Site Leader	Virginia Commonwealth University
David Wright, MD	Study Site Leader	Emory University
David Schnyer, PhD	Study Site Leader	UT Austin
Richard 'Ben' Rodgers, MD	Study Site Leader	Indiana University
Vincent Wang, MD PhD	Study Site Leader	UT Houston
Mike McCrea, PhD	Study Site Leader	Medical College of Wisconsin
Ramesh Grandhi, MD MS	Study Site Leader	University of Utah
Andrew Maas, MD	Member; PI of CENTER-TBI/InTBIR	Antwerp University Hospital, Belgium
David Menon, PhD	Member; Co-PI of CENTER-TBI/InTBIR	University of Cambridge, Cambridge
Isabelle Gagnon, MSc PhD	Member, PI Canadian Institutes of Health	McGill University Health Centre

2. PROCESS FOR RESEARCH COLLABORATION REQUESTS

Access to study data, biospecimen materials sharing, and mutual collaboration among research teams in order to accelerate research in TBI are fundamental tenets of the TRACK-TBI project and are core beliefs of its investigators. The TRACK-TBI Dataset and repositories can only serve their intended purposes as a current and legacy resource for further research with a robust, transparent, and open-access collaboration policy. To ensure optimal use and to limit possible misuse of the data and materials derived from an effort of this magnitude, the TRACK-TBI Executive Committee will monitor all ongoing Research Collaborations.

The TRACK-TBI Executive and Steering Committees will not entertain unfunded collaborations that increase cost to the TRACK-TBI study. Furthermore, all potential collaborations must not interfere with or otherwise compromise the specific aims, outcomes, follow-up rates, or integrity of the parent TRACK-TBI study objectives and mandates.

2.1 Research Collaboration Requests

All Research Collaborations with TRACK-TBI will begin with a written request submitted to the TRACK-TBI Executive Committee. The Research Collaboration Proposal form is attached here as Appendix 1. Completed Research Collaboration Proposal forms are to be submitted to Dr. Geoffrey Manley, Contact PI for TRACK-TBI, in care of Brian Fabian (Brian.Fabian@ucsf.edu).

Research Collaboration Requests will include notation of the TRACK-TBI PI who will serve as a sponsor of the proposal, a table of authors and their affiliations, the study aims and sub-aims, and a description of the methodologies and approaches to be used to address the scientific questions involved.

The Research Collaboration Request will also provide a proposed budget (see Section 6 below).

Upon receipt, research collaboration requests will be screened by the TRACK-TBI Ombudsperson to identify and/or mitigate circumstances in which an overlap may occur in research aims, proposed methods, or analytical design with other TRACK-TBI work, whether currently proposed or previously approved. Once vetted and cleared by the Ombudsperson, the collaboration request will then be circulated to the TRACK-TBI Executive Committee for review, and approval/rejection/request for revision. Please allow 4-6 weeks for this process.

2.2 Data Use Agreements

The Data Use Agreement/Human Materials Transfer Agreement (DUA/HTMA) for TRACK-TBI Research Collaborations is attached as Appendix 2. This Agreement is for the use of clinical data, neuroimaging, and biospecimens collected by the TRACK-TBI investigators.

The DUA/HTMA must be endorsed by the Organization Principal Investigator for the collaborating entity, and its institutional signatory, as well as UCSF.

3. INTELLECTUAL PROPERTY

Management of intellectual property rights, including copyright, will be handled by the Office of Technology Management at the University of California, San Francisco, in accordance with applicable University of California policies governing intellectual property rights.

4. AUTHORSHIP AND PUBLICATIONS

Any publications that emerge from use of TRACK-TBI data and material are subject to the review and authorship acknowledgments set forth in the TRACK-TBI DUA/HTMA (Appendix 2) and Publication and Authorship Guideline (Appendix 3).

In the spirit of collaboration, all publications will be joint publications with Data Contributors, Collaborators, and TRACK-TBI Investigators.

All efforts will be made to protect proprietary information or intellectual property that might be disclosed by the manuscript or abstract.

Failure to comply with authorship and publication expectations will result in termination of the Research Collaboration Agreement(s).

5. CONFLICT OF INTEREST

Researchers involved in collaborative research projects must disclose and manage any actual or apparent conflicts of interest relating to any aspect of the research collaboration with the TRACK-TBI study in accordance with the Conflict of Interest Policy of the University of California, San Francisco.

6. BUDGET

The goal of research collaboration with TRACK-TBI is to build intellectual synergism that will enhance the objectives of the TRACK-TBI study and serve public health. TRACK-TBI on its own, does not have adequate funding, resources, or intellectual capacity to maximize its potential impact on traumatic brain injury and public health. Forming strategic collaborations can be an effective and economical way of accessing resources and may lead to longer-term partnerships.

Nevertheless, the scope of work for any and all collaborations with external parties must be accounted for with appropriate resources. The budget must be an accurate reflection of the amount and the timing of the resources required for the collaborative project, as included in the Research Collaboration Request Form.

There must be enough funding to undertake the proposed collaboration without detracting from other efforts and core deliverables already underway. Staff time in managing and executing the collaboration must be reflected in the budget. In-kind contributions from corporate collaborators will be taken into consideration in the overall budget assessment.

The budget provided in the Research Collaboration Request must specify when payments will be made and clearly indicate when the contributed in-kind resources, if any, will be provided. Failure to adhere to the specified, agreed-upon budget will result in termination of the Research Collaboration Agreement and any and all attendant Data Use or Material Transfer Agreements.

7. TERMINATION OF RESEARCH COLLABORATION AGREEMENTS

All Research Collaboration Agreements with TRACK-TBI will have a specified date upon which the research collaboration project will end. The end date may be extended through the amendment process, if both parties agree.

The TRACK-TBI Leadership reserves the right to terminate a Research Collaboration Agreement or DUA/HTMA before the end date at the discretion of the Executive Committee with a 30-day written notice.

Appendix 1: Research Collaboration Proposal Request Form

Instructions: A completed and approved Research Collaboration Proposal Request is required to be submitted to the TRACK-TBI Executive Committee (care of brian.fabian@ucsf.edu) and should be no more than 2 pages long. Authors are encouraged to contact the Biostatistics Core to receive assistance with the statistical analysis plan. Clinical site statisticians are also encouraged to participate in these consultations. Proposals will be reviewed by the TRACK-TBI Executive Committee. All aspects of manuscript development will be governed by this Guideline. Proposals should contain the following elements:

Date:

Investigator's Name: Investigator's Title:

Organization or Clinical Center:

E-mail: Telephone:

TRACK-TBI Sponsor (if not a TRACK-TBI investigator):

Other investigators who will be working on this analysis:

Analysis Plan Title:

TRACK-TBI Dataset files requested: Pilot Study ☐ TRACK-TBI U01 Study ☐ Biospecimen request ☐

Purpose of Data Request (check all that apply)		**TRACK-TBI Core (check all that apply)**	
☐	Exploratory	☐	Clinical Core
☐	Data analysis for manuscript	☐	Biospecimens Core
☐	Preliminary data for grant proposal	☐	Neuroimaging Core
☐	Inputs for simulation model	☐	Biostatistics/CER Core
☐	Development of statistical methods	☐	Outcomes Core
☐	Other (describe)		

Please attach a 2-page description of your analysis plan including:

1) Short background/rationale for addressing the research question
2) Primary variables to be used in the analysis (please provide mock tables)
3) Brief description of methods and statistical analysis plan
4) What is the impact if successful?

For exploratory requests, complete item 1 now and submit items 2 through 4 within 60-days of accessing the dataset(s).

Appendix 2: TRACK-TBI Data Use Agreement/Human Materials Transfer Agreement

TRACK-TBI
Data Transfer Agreement and Human Material Transfer Agreement

This Data Transfer Agreement and Human Material Transfer Agreement ("DTA/HMTA") is between The Regents of the University of California, on behalf of its San Francisco campus ("UCSF") and _____ ("Data User") and is effective as of the date of last signature "Effective Date." Data User is entering into this Agreement on behalf of its employee, Dr. _____ (the "Data User Principal Investigator") who is not a party to this Agreement.

UCSF and Data User are hereinafter also referred to individually as "Party" and collectively as "Parties".

Preamble:

1. The Parties wish to collaborate and share data with the ultimate goal of furthering progress in research on traumatic brain injury related to the specific aims of the Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI NINDS Grant# U01 NS1365885) study and any adjunct research activities generated by TRACK-TBI; and

2. Under this Agreement's terms and conditions, Data User will be provided access to original or derivative clinical data file(s) ("Clinical Data") and/or human materials (hereafter "Biospecimens") and/or neuroimaging studies ("Imaging Studies"), provided that the TRACK-TBI Executive Committee ("Executive Committee") has approved the transfer of Clinical Data, Biospecimens, and/or Imaging Studies.

3. The Parties acknowledge the Clinical Data, Biospecimens, and/or Imaging Studies, have been collected as part of the TRACK-TBI study with the undertaking to provide UCSF as the administrative custodian ("Custodian"). Such information is integrated and stored as part of the TRACK-TBI dataset on a data integration platform or repository, as relevant ("Repository or "Repositories"); and

4. The TRACK-TBI Executive Committee ("Executive Committee") controls decisions surrounding the storage and use of such data in the Repository; and

5. The Parties acknowledge that any publications or presentations generated from investigation and analysis of TRACK-TBI are governed by policies set forth in the TRACK-TBI Publication and Authorship Guideline incorporated herein by reference, subject to future amendment by TRACK-TBI Executive Committee as needed, along with recognition and disclosure of the source grant(s) for the utilized dataset(s).

6. Notification shall be in writing either electronic or by mail:

UCSF Principal Investigator ("PI") facilitating this Agreement for Custodian:
Geoffrey T. Manley, MD, PhD
Study Title: TRACK-TBI
Address:
University of California, San Francisco
Department of Neurological Surgery
Brain and Spinal Injury Center
1001 Potrero Avenue, Bldg. 1, Room 101
San Francisco, California
Contact: email: manleyg@ucsf.edu tel: 415-206-8300

Administrative Contact for Custodian:
The Regents of the University of California, on behalf its San Francisco Campus
Address:
UCSF – Industry Contracts Division
490 Illinois St., 5th Floor
San Francisco, CA 94143
Contact: industrycontracts@ucsf.edu

7. Except as otherwise specified herein, the Data User may make all uses and disclosures of the sample of the de-identified Clinical Data, Biospecimens, and/or Imaging Studies, to conduct the Research Project as described in Data User's Research Proposal (Exhibit A) and this section. For the purposes of the Agreement, derivative data file(s) are any and all data file(s) created using the original data in any way. This Agreement addresses the terms and conditions pursuant to which the Data User is permitted to obtain, use, reuse, and disclose the Clinical Data, Biospecimens, and Imaging Studies, or derivatives of any. TRACK-TBI retains all applicable rights to the Clinical Data, Biospecimens, and/or Imaging Studies referred to in this Agreement, and the Data User does not obtain any intellectual property rights related to, or any other right, title, or interest in any of the Clinical Data, Biospecimens, and/or Imaging Studies or derivatives other than those which are expressly granted in this Agreement. Data User understands and acknowledges that the Clinical Data, Biospecimens, and/or Imaging Studies may be protected by copyright and other intellectual property rights, and that duplication, except as reasonably necessary to carry out the Research Proposal, or sale of all or part of the Clinical Data, Biospecimens, and/or Imaging Studies is expressly prohibited.

a) The following original Clinical Data are being made available pursuant to this Agreement for research purposes

De-identified clinical data from TRACK-TBI U01 dataset

b)The following Biospecimens are being made available pursuant to this Agreement for research purposes:

De-identified biospecimen data derived from TRACK-TBI U01 dataset

c) The following original Imaging Study Files are being made available pursuant to this Agreement for research purposes:

De-identified imaging data derived from TRACK-TBI U01 dataset

8. Access to TRACK-TBI and/or access to Clinical Data, Biospecimens, and/or Imaging Studies is provided to Data User for the purpose of ongoing collaboration in TBI research and will be used only as described in Research Proposal.

9. Data User will provide to UCSF a Research Completion Report on a form to be provided by UCSF PI, upon completion of the agreed project. The Research Completion Report shall include a recitation of the findings of the project, and a copy of all derivative data that Data User develops in the course of the project. The Report will contain a completed form (the "Minimal Dataset Form") that describes the "minimal dataset" – that is, the dataset used to reach the conclusions reached in the report and any manuscript produced, with related metadata and methods, and any additional data required to replicate the reported study findings in their entirety. Core descriptive data, methods, and study results should be included within the report, regardless of data deposition.

10. Data User certifies to the best of its knowledge that the facts and statements made by Data User in the Research Proposal are complete and accurate.

11. Data User certifies to the best of its knowledge that the requested Clinical Data, Biospecimen data, and/or Imaging data are the minimum necessary to achieve the purposes set forth in the Research Proposal.

12. Data User certifies to the best of its knowledge that it has obtained Institutional Review Board approval to use the Clinical Data, Biospecimen data, and/or Imaging data.

13. Data User certifies to the best of its knowledge that it has sufficient resources to and intends to complete the research project as set forth in the Research Proposal.

14. Data User agrees to use the Clinical Data, Biospecimen data, and/or Imaging data strictly in accordance with applicable local and federal laws, including but not limited to the following related to confidentiality, privacy, and security regulation:

    i. The Privacy Act of 1974, as most currently amended
    ii. California's Confidentiality of Medical Information Act (CMIA)

iii. "HIPAA": the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191. The data provided to UCSF is de-identified in accordance with the de-identification standards set forth under the Health Insurance Portability and Accountability Act (HIPAA) and all implementing regulations, including, but not limited to 45 CFR § 164.514(a)-(c) and § 164.502(d) as well as applicable human subjects regulations and guidance, 45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56

15. Data User will receive access to de-identified data and will not attempt to establish the identity of, or attempt to contact any of the individuals, whose data are contained in the TRACK-TBI dataset.

16. Data User and members of their research team that are under the direct supervision of the Data User shall be entitled to use Clinical Data, Biospecimen data, and/or Imaging data from the TRACK-TBI dataset, and agree to do so in a secure manner using appropriate administrative, physical storage and technical safeguards to prevent use or disclosure of such in ways other than are permitted under this Agreement. All personnel certify that they have completed a Collaborative Institutional Training Initiative (CITI Program) module, with specific certification in Human Subjects Protection Training.

17. Except as otherwise required by law, any transfer to or from third parties of Clinical Data, Biospecimens, and/or Imaging Studies is prohibited without authorization from the TRACK-TBI Executive Committee with the exception that Data User may transfer to, and permit the use of such by the subcontractors or collaborators listed in Research Proposal to aid in the performance of the Research Project under a data transfer and human materials transfer agreement with terms that are no less strict than the terms of this Agreement. It is incumbent on the Data User to seek out and engage in separate agreements to the extent that the relevant data is shared with non-UCSF third parties such as other repositories or collaborators providing Clinical Data, Biospecimens, and/or Imaging Studies. These separate agreements shall not contain terms that conflict with the rights and obligations under this Agreement of UCSF, the TRACK-TBI Executive Committee, or the Data User, and shall have no less stringent obligations than are imposed under this Agreement. Under these separate agreements, the terms of this agreement shall be incorporated by reference, including but not limited to those contained in the TRACK-TBI Research Collaboration Policy and the TRACK-TBI Publication and Authorship Guideline.

18. If the Data User Principal investigator moves to another institution or company, Data User will notify the UCSF Principal Investigator in writing within 30 days regarding disposition of the TRACK-TBI Clinical Data, Biospecimens, and/or Imaging Studies in possession or control by Data User.

19. Data User agrees to notify UCSF and its Principal Investigator within 2 days of becoming aware of any use or disclosure of the Data in violation of the law or of this Agreement.

20. The TRACK-TBI dataset as a whole, and any of its constituent data, are experimental in nature and are provided without any warranties, express or implied, including any warranty of merchantability, accuracy, or fitness for a particular purpose. UCSF makes no representation and provides no warranty that the use of the TRACK-TBI dataset will not infringe any patent or other proprietary rights.

21. To the extent allowable under applicable laws, Data User agrees to indemnify, defend and hold harmless UCSF and its trustees, officers, staff, representatives and agents against all damages, expenses (including without limitation legal expenses), claims, demands, suits or other actions arising from Data User's negligence or intentional misconduct in its acceptance, storage, use and disposal of the TRACK-TBI dataset, as well as all other information provided to Data User under this Agreement or arising in connection with this Agreement.

22. This Agreement is not assignable by Data User.

23. Neither Party will use the name of the other Party or its employees in any advertisement, press release, or other publicity without prior written approval of the other Party.

24. The term of this Agreement shall commence on the Effective Date (indicated above) and shall continue for a period of three (3) years, unless terminated sooner as set forth in this Agreement. This Agreement may be renewed for additional one (1) year terms by written amendment signed by authorized officials of both parties.

25. Upon termination or expiration of this Agreement, the Data User agrees to promptly provide UCSF with a summary of the results of the research conducted using the TRACK-TBI dataset in accordance with the Research Proposal ("Research Summary"), as well as all materials and data provided by TRACK-TBI under this Agreement, without limitation. The Data User further agrees to promptly provide UCSF with a Research Summary prior to the execution of a written amendment to extend the term of this Agreement.

26. Either Party may terminate this Agreement upon thirty (30) days prior written notice to the other party.

27. Upon termination of this Agreement, Data User shall at UCSF's option, return or destroy (and confirm in writing such destruction), the Clinical Data, Biospecimen data, and/or Imaging data and all copies, including all documents created by Data User where portions of the TRACK-TBI dataset, Clinical Data, Biospecimen data, and/or Imaging data are reproduced. Use of the Clinical Data, Biospecimen data, and/or Imaging data for a new purpose or project will require a new application to and subsequent approval by Executive Committee.

28. This Agreement may be executed in one or more counterparts. Delivery of an executed counterpart of this Agreement by facsimile or a .pdf data file or other scanned executed counterpart by email shall be equally as effective as delivery of a manually executed counterpart of this Agreement.

Signatures

If Data User and Data User principal investigator acknowledge and agree to the above terms and conditions for transfer of the TRACK-TBI dataset Clinical Data, Biospecimen data, and/or Imaging data, please so indicate by returning one copy of this Agreement signed and dated by Data User principal investigator and by a duly authorized representative of Data User. Upon receipt of signed Agreement by UCSF Principal Investigator and UCSF authorized representative, and confirmation that CITI Human Subjects Protection Training certification has been completed, the Data described in Paragraphs 7(a)-(c) will be provided to Data User for the purposes set forth in Research Proposal. **All members of Data User's Research Team who will access or analyze data must individually sign this Agreement.**

READ & ACKNOWLEDGED

DATA USER or PRINCIPAL INVESTIGATOR

Signature: _____

Printed Name: _____

Title: _____

Date: _____

Signature: _____

Printed Name:

Title: _____

Date: _____

AUTHORIZED SIGNATORY FOR DATA USER INSTITUTION

Signature: _____

Printed Name: _____

Title: _____

Date: _____

AUTHORIZED SIGNATORY FOR UCSF

Signature: _____

Printed Name: _____

Title: _____

Date: _____

READ AND ACKNOWLEDGED BY UCSF PRINCIPAL INVESTIGATOR

Signature: _____

Printed Name: _____

Title: _____

Date: _____

Appendix A

Appendix 3: TRACK-TBI Publication and Authorship Guideline

This **Publication and Authorship Guideline** has been established by the TRACK-TBI Executive Committee for the publication of data collected under the protocol entitled: Transforming Research and Clinical Knowledge in TBI (TRACK-TBI). TRACK-TBI is governed by data use guidelines, as described in the TRACK-TBI Research Collaboration Policy and Data Use Agreement/Human Materials Transfer Agreement. This Publication and Authorship Guideline will be in effect until such time as the data may become publicly accessible, and is subject to amendment by the TRACK-TBI Executive Committee.

This guideline addresses three major types of manuscripts. **Primary manuscripts** are those that report the conduct and outcome of the major objectives of the trial (i.e., the major results of the collaboration). **Secondary manuscripts** refer to secondary hypotheses and ancillary analyses that come from data that were collected for this study. **Tertiary manuscripts** are those in which data collected are used as an illustrative example of a proposed preferred methodology or studies for which ancillary data, unrelated to the primary study hypotheses, are collected, sometimes on only a subset of study sites. All data presentations, including abstracts, oral presentations, and posters, are encompassed by the term "manuscript."

General Principles

1. This guideline may be subject to ongoing interpretation by the Executive Committee. Experience and new insights from this trial may necessitate periodic modification by consensus of the Executive Committee.

2. No TRACK-TBI data shall be presented, submitted or published in any way without the express prior written approval of the Executive Committee.

3. 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). Primary authors should meet all four of the following criteria:

    1) Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; AND
    2) Drafting the work or revising it critically for important intellectual content; AND
    3) Final approval of the version to be published; AND
    4) 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.

4. Authorship credit will be granted to the primary authors ***with the TRACK-TBI Investigators as an author***. Following the list of primary authors, all publications using TRACK-TBI data will bear the following attribution: "and the TRACK-TBI Investigators" listed in alphabetic order. Including the TRACK-TBI Study Investigators allows all members to be indexed as authors (not contributors) in PubMed.

5. Responsibilities and tasks for production of primary manuscripts will be determined by the Executive Committee and the Biostatistical Core. The results to be included in the primary manuscript will be presented to the Executive and Steering Committees for review and response.

6. Secondary and tertiary manuscripts are strongly encouraged and may be initiated by any participating TRACK-TBI investigator. Two-page proposals for secondary and tertiary manuscripts must include a tentative title, primary author(s), background/rationale, and statistical analysis plan (NOTE: see Appendix 1 to Research Collaboration Agreement) and must be submitted to the Executive Committee in care of Contact Principal Investigator, Geoffrey T. Manley, MD PhD via the Project Administrator (brian.fabian@ucsf.edu). Consultations with the Biostatistical Core are essential to developing adequate statistical plans prior to final submission to the Executive Committee. Clinical site statisticians and epidemiologists are encouraged to participate in these consultations, which should take place after proposal submission to, and acceptance by the Executive Committee. Of note, as analyses are developed

and when they are complete, where relevant, manuscripts should specify the amount and assumptions being made about the mechanism of missing data, i.e. whether the data are missing at random (MAR), missing completely at random (MCAR), or not missing at random (NMAR) for the proposed analyses. A detailed explanation for how missing data are to be/were handled should be provided, including statistical approaches and sensitivity analyses. We strongly recommend that collaborators adhere to guidelines described in Nielson et al. 2020 (https://pubmed.ncbi.nlm.nih.gov/32008424/) and Richter et al. 2020. (https://pubmed.ncbi.nlm.nih.gov/31062649/) All submitted and finalized proposals will be posted on the TRACK-TBI Idea Board for review and comment by all TRACK-TBI PIs and co-Is.

7. Each secondary and tertiary manuscript proposal will identify a primary author/writing group leader, who will be responsible for assigning tasks to members of the writing group. To uphold the authorship criteria presented in General Principle 3, 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 sole responsibility for ensuring that authorship order has been discussed and confirmed by co-authors. There is no prescribed limit of authors from each institution; however, each named author must have contributed significantly to the manuscript as described above. If there is a disagreement among the potential co-authors, the Executive Committee will determine inclusion of an author and/or order. If agreement cannot be reached by the Executive Committee, Michael Weiner, MD PhD, of the TRACK-TBI Scientific Advisory Board will be the tie-breaker and serve as mediator. For secondary (and possibly tertiary) manuscripts, the author list will include the named authors followed by "and the TRACK-TBI Study Investigators."

8. After manuscripts have been prepared, revised, and readied for submission by the main authors, 2 weeks prior to intended submission, the first author will be responsible for sending the manuscript to Brian Fabian (brian.fabian@ucsf.edu) who will send it to the wider 50+ group of TRACK-TBI Investigators for comments and/or revisions. If an investigator sends comments or revisions, they will automatically be included in the larger author block cited in the Acknowledgements section of the manuscript. If an investigator does not have revisions or comments, but would still like to be included in the author block based on their contributions to TRACK-TBI, they must reply within the one-week review period confirming their intent to be included, and the agreement that you will respond to the journal's request for authorship forms or copyright assignment within 48 hours of receipt. If an investigator does not communicate their intent to be included in the larger author block, it will be assumed that you do not want to not be included in the "TRACK-TBI Investigators" author block for the manuscript and you will be removed.

9. Before submission of an abstract to a scientific meeting, it is expected that the associated data analyses and interpretation will be completed. It is expected that the resultant manuscript will be submitted to a journal by or before 3 months following presentation of the abstract at the scientific meeting.

10. If preparation and submission of manuscripts is not accomplished in a timely manner (within six months following the receipt of data), the Executive Committee reserves the right to delegate manuscript-writing responsibility to another investigator. These requirements are in place to ensure the timely publication and dissemination of study results to the public and the scientific community.

11. Using TRACK-TBI data as preliminary data for grant submission by investigators at participating institutions is encouraged. However, any data tables included in a grant proposal must be approved by the Executive Committee before submission.

12. The Executive 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 parties obtaining access to the data will agree to abide by the obligations of the TRACK-TBI DUA/HTMA and as set forth in this Guideline.

13. All authors are responsible for notifying the Executive Committee (via email to Brian Fabian brian.fabian@ucsf.edu) 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 TRACK-TBI Administrative Core will maintain a central list of all accepted abstracts, presentations and publications relating to TRACK-TBI, which will be posted on the TRACK-TBI website.

Acknowledgements

1. As this study was sponsored by external sources, an acknowledgement is required on all publications.

   "Sponsored by the U.S. National Institutes of Health, National Institute of Neurologic Disorders and Stroke (Grant # TRACK-TBI NINDS Grant# U01 NS1365885), and our public and private partners. The opinions or assertions contained here are the private views of the authors and are not to be construed as official or as reflecting the views of any sponsor."

2. Contributions from other collaborators, including laboratory, economists, scientists, consultants or other individuals providing expertise during the trial design, conduct and manuscript processes but not members of the official TRACK-TBI Study Investigators and not meeting the prescribed authorship criteria should also be listed in the acknowledgments.

TRACK-TBI Executive Committee		
Name	Role	Institution
Geoffrey Manley, MD, PhD	Contact PI, Admin Core Leader	UCSF
Ramon Diaz-Arrastia, MD	PI, Emerging Tech Core Leader	University of Pennsylvania
Joseph Giacino, PhD	PI, Clinical/Rehab Core Leader	Spaulding Rehabilitation Center
Pratik Mukherjee, MD PhD	PI, Neuroimaging Core Leader	UCSF
David Okonkwo, MD PhD	PI, Clinical/Rehab Core Leader	University of Pittsburgh
Murray Stein, MD MPH	Outcomes Core Co-Lead	University of California, San Diego
Nancy Temkin, PhD	PI, Biostatistics Core Leader	University of Washington
Claudia Robertson, MD	PI, Clinical/Rehab Core Leader	Baylor College of Medicine

TRACK-TBI Steering Committee		
Name	Role	Institution
Geoffrey Manley, MD PhD	Contact PI, Admin Core Leader	UCSF
Ann-Christine Duhaime, MD	Clinical Core Co-Leader (Pediatrics), Site Leader	Harvard Medical School
C. Dirk Keene, MD PhD	Pathology Core Leader	University of Washington
Laura Ngwenya, MD PhD	Study Site Leader	University of Cincinnati
Neeraj Badjatia, MD	Study Site Leader	University of Maryland
Randall Chesnut, MD	Study Site Leader	University of Washington
Gillian Hotz, PhD	Study Site Leader	University of Miami
Christopher Madden, MD	Study Site Leader	UT Southwestern
Alex Valadka, MD	Study Site Leader	Virginia Commonwealth University
David Wright, MD	Study Site Leader	Emory University
David Schnyer, PhD	Study Site Leader	UT Austin
Richard 'Ben' Rodgers, MD	Study Site Leader	Indiana University
Vincent Wang, MD PhD	Study Site Leader	UT Houston
Mike McCrea, PhD	Study Site Leader	Medical College of Wisconsin
Ramesh Grandhi, MD	Study Site Leader	University of Utah
Andrew Maas, MD	Member; PI of CENTER-TBI/InTBIR	Antwerp University Hospital, Belgium
David Menon, PhD	Member; Co-PI CENTER-TBI/ InTBIR	University of Cambridge, Cambridge

READ AND ACKNOWLEDGED

Signature: _____

Printed Name: _____

Title: _____

Date: _____

Appendix 4: Biospecimen Sharing Policy

Data sharing and mutual collaboration among research teams to accelerate research in TBI is a fundamental tenet of the TRACK-TBI project, and are core beliefs of its investigators. The TRACK-TBI database and biospecimen repositories can only serve their intended purposes as a current and legacy resource for further research with a robust, transparent, and open-access data and biospecimen sharing plan. Plasma and serum samples from the currently enrolling study (U01NS086090) are a finite resource and governed by this TRACK-TBI Biospecimen Sharing Policy, **which is part of, and incorporates by reference the terms of the TRACK-TBI Research Collaboration Policy and its Data Use/Human Materials Transfer Agreements and Publication and Authorship Guidelines, which agreements must be acknowledged and/or executed as part of any approved request to share TRACK-TBI biospecimens.**

All biospecimen requests must originate with submission of the TRACK-TBI Research Collaboration Request Form and preliminary analysis plan to the TRACK-TBI Administrative Core (Appendix 1). Requests are reviewed by the TRACK-TBI Executive Committee for review and decision.

Study Purpose

- The purpose of TRACK-TBI plasma and serum samples is to serve as a validation cohort. **Requests for samples to be used in a discovery cohort or for an exploratory study will not be entertained.**
- Requests for samples must be accompanied with preliminary data from humans with TBI, showing in small- to moderate-sized cohorts that the biomarker(s) being proposed show promise as a diagnostic or prognostic biomarker for TBI. Preliminary results from animal models or humans with other disorders (i.e., stroke, epilepsy) are not sufficient.
- Due to the complex nature of the clinical data collected and its relationship with the biofluid biomarkers, analysis should be carried out in collaboration with a TRACK-TBI Investigator. This Investigator must be identified on the Research Collaboration Request Form.

Specimen Allocation and Disposition

The minimum volume of sample required for the proposed studies will be provided. Only in exceptional circumstances will more than 0.15 mL be provided, and those will be have be well justified.

Plasma OR serum samples will be provided to collaborators de-identified and blinded.

Samples will be shipped by TRACK-TBI Biorepository staff at University of Pittsburgh Medical Center (UPMC) and will require execution of an MTA with University of Pittsburgh. (Appendix 2)

A shipping and handling fee will be applied to each shipment based on the nature of the request.
Samples are only to be used to run assays on the biomarkers proposed in the collaboration agreement.
Any volume of unused biospecimen must be returned to the TRACK-TBI Biorepository within 120 days.
Returning samples to the TRACK-TBI Biorepository should follow the shipping instructions in the TRACK-TBI Biorepository SOP.

Results must be returned to TRACK-TBI and will be deposited together with TRACK-TBI data in the Federal Interagency TBI Repository (FITBIR). Access to this data will be according to FITBIR policies.

Process for Requesting Biospecimen Samples

1. Submit TRACK-TBI Research Collaboration Request Form: 2-page description of analysis plan and amount of plasma/serum requested.
2. Collaboration/biospecimen request considered by TRACK-TBI Executive Committee.
3. Following approval of collaboration/biospecimen request, a worksheet will be completed by the collaborator

that will allow the TRACK-TBI Biorepository at University of Pittsburgh to calculate processing, handling, and shipping fees.

4. A Data Use Agreement/Human Materials Transfer Agreement (Appendix 2) then must be fully executed between the collaborator and TRACK-TBI by the UCSF PI (Appendix 1) and independently between collaborator and University of Pittsburgh. (Appendix 2)
5. Biospecimen samples are shipped by TRACK-TBI Biorepository at University of Pittsburgh to collaborator.