



TBI Endpoints Development Initiative

A collaborative for advancing diagnosis and treatment of TBI

TBI ENDPOINTS DEVELOPMENT (TED) INITIATIVE METADATASET DATA USE AGREEMENT AND HUMAN MATERIAL TRANSFER AGREEMENT

This Data Use Agreement and Human Material Transfer Agreement (“DUA/HMTA”) is between The Regents of the University of California, on behalf of its San Francisco campus (“UCSF”) and [INSERT NAME OF INSTITUTION on behalf of Principal Investigator and PI] (“Data User”) and is effective as of the date of last signature “Effective Date.”

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 TBI Endpoints Development Study (TED) initiative and any adjunct research activities generated by the TED initiative; and
2. Under this Agreement’s terms and conditions, Data User will be provided access to original and/or derivative clinical data file(s) (“Clinical Data”), and/or human materials (hereafter “Biospecimens”), and/or neuroimaging studies (“Imaging Studies”), provided that TED Executive Committee (“Executive Committee”) has approved the transfer of Biospecimens, Imaging Studies, and/or Data.
3. The Parties acknowledge the Clinical Data, Biospecimens, and/or Imaging Studies have come in through related Data Contribution and Use Agreements (“DCUAs”) from collaborators in the field of traumatic brain injury (“Data Contributors”) with the undertaking to provide UCSF as the administrative custodian (“Custodian”), information that is integrated and stored as part of the TBI Endpoints Initiative’s “TED Metadataset,” on a data integration platform or repository, as relevant (“Repository” or “Repositories”); and
4. The TED 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 the TED Metadataset are governed by policies set forth in the TED Publication and Authorship Guideline incorporated herein by reference, subject to future amendment by TED Executive Committee as needed, along with recognition and disclosure of the source grant(s) for the utilized dataset(s).
- 6 Data User will also have the opportunity to explore the TED Metadatset pursuant to the TED Research Collaboration Policy, incorporated here by reference, subject to future amendment by the TED Executive Committee as needed.
7. 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: TED

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, USA

Contact: Email: manleyg@neurosurg.ucsf.edu Tel: 415-206-8300 Fax: 415-206-3948

Administrative Contact for Custodian:**The Regents of the University of California, on behalf its San Francisco Campus****Address:** UCSF - Office of Innovation, Technology, & Alliances
3333 California St., S-11
San Francisco, CA 94143-1209**Contact:** industrycontracts@ucsf.edu**Data User Agreements and Obligations**

8. 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/or Imaging Studies, or derivatives of any. Data Contributor 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 not permitted.

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

Name of Study Providing the Biospecimens, Imaging Studies, and/or De-Identified Data**[insert list]**

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

Name of Study Providing the Biospecimens, Imaging Studies, and/or De-Identified Data**[insert list]**

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

Name of Study Providing the Biospecimens, Imaging Studies, and/or De-Identified Data**[insert list]**

9. The TED Metadataset access 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.

10. 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.

11. The facts and statements made by Data User in the Research Proposal are complete and accurate;

12. The requested Clinical Data, Biospecimens, and/or Imaging Studies are the minimum necessary to achieve the purposes set forth in the Research Proposal;

13. Data User has obtained Institutional Review Board approval to use the Clinical Data, Biospecimens, and/or Imaging Studies;

14. Data User has sufficient resources to and intends to complete the research project as set forth in User's Research Proposal; and

15. Data User agrees to use the Clinical Data, Biospecimens, and/or Imaging Studies 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

16. 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 TED Metadataset.

17. 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, Biospecimens, and/or Imaging Studies from the TED Metadataset, 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.

18. 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 TED 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 use 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 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 TED Executive Committee, or the Data User or Data Contributor, 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 through reference, including but not limited to those contained in the TED Research Collaboration Policy and the TED Publication and Authorship Guideline.

19. If Data User moves to another institution or company, Data User will notify the UCSF Principal Investigator in writing within 30 days regarding disposition of the TED Metadataset as well as the Clinical Data, Biospecimens, and/or Imaging Studies in possession or control by Data User.

20. Data User and Other Users entitled to use the Data from the TED Metadataset agree to notify the UCSF Principal Investigator within 2 days of becoming aware of any use or disclosure of the Data in violation of the law or this Agreement.

21. The TED Metadataset 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 Data Contributors' Data or the TED Metadataset will not infringe any patent or other proprietary rights.

22. 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 Data Contributors' Data and TED Metadataset, as well as all other information provided to Data User under this Agreement or arising in connection with this Agreement.

23. This Agreement is not assignable by Data User.

24. 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.

25. The term of this Agreement shall commence on the Effective Date (indicated above) and shall continue for a period of two (2) 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.

26. 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 TED Metadataset in accordance with the Research Proposal ("Research Summary"), as well as all materials and data provided by Data Contributors and UCSF 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.

27. The Data User may terminate this Agreement at any time by notifying the UCSF Principal Investigator in writing, and promptly returning all Data provided to Data User under this Agreement.

28. UCSF or the TED Executive Committee may terminate this Agreement at any time by denying the Data User's access to additional data and other study materials. UCSF may terminate with or without cause, for any reason, and shall indicate so in writing to Data User. In the event that UCSF terminates this Agreement, Data User shall at UCSF's option, return or destroy (and confirm in writing such destruction), the Clinical Data, Biospecimens, and/or Imaging Studies and all copies, including all documents created by Data User where portions of the TED Metadataset, Biospecimens, and/or Imaging Studies are reproduced. Use of the Clinical Data, Biospecimens, and/or Imaging Studies for a new purpose or project will require a new application to and subsequent approval by Executive Committee.

29. 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 TED Metadataset Clinical Data, Biospecimens, and/or Imaging Studies, 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 8 (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 AND ACKNOWLEDGED

DATA USER or PRINCIPAL INVESTIGATOR

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: _____

EXHIBIT A

Research Proposal