



Department of Neurological Surgery
Brain and Spinal Injury Center

DATA USE AGREEMENT

This Data Use Agreement (“Agreement”) is entered into by and between The Regents of the University of California, on behalf if its San Francisco campus (“UCSF” or “Data User”), and [full legal name of entity]_____ having a principal place of business located at [address]_____ (“Data Contributor” or “Covered Entity”) and shall be effective as of _____ (the “Agreement Effective Date”)

UCSF and Data Contributor 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; and
2. Data Contributor undertakes to provide to UCSF as the custodian, certain data to be integrated and stored as part of the TED MetaDataset, on a data integration platform (the “Repository”); and
3. The Parties acknowledge this Data Use Agreement relates to the separate DUA between UCSF and such Repository; and
4. The TED Executive and Steering Committees control decisions surrounding the storage and use of such data in the Repository; and
5. The Parties acknowledge that any publications generated from the TED MetaDataset using the Data Contributor's Data will include Data Contributor and other investigators Data Contributor identifies in Data Contributor Information below in the author block for such publications, along with recognition and disclosure of the source grant(s) for Data Contributor's dataset, as set forth in the TED Publication and Authorship Guidelines incorporated here by reference, subject to future amendment by the TED Executive Committee as needed; and
6. Data Contributor 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;

NOW THEREFORE, in consideration of the premises and mutual covenants herein contained, the Parties agree to the following:

Data Contributor Information

List information for Organization Principal Investigator (“Data Contributor” or “You”) and include any co-investigators, subcontractors, students, fellows or staff.

Organization	
Name of Principal Investigator	
Title	
Institution/Department	
Address 1	
Address 2	



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City, State, Zip			
Phone		Fax	
Email			
Title of Project			
List of any Co-investigators, Subcontractors, Students, Fellows or Staff			
Description of Data Contributor Data			

Name of UCSF Principal Investigator facilitating this Agreement and data sharing:

Geoffrey T. Manley, MD, PhD
Professor and Vice Chairman of Neurological Surgery
University of California, San Francisco
Chief of Neurosurgery, San Francisco General Hospital
Co-Director, Brain and Spinal Injury Center (BASIC)
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1. **Definitions.** The parties agree that the following terms when used in this Agreement shall have the following meanings and that the terms set forth below shall be deemed to be modified to reflect any changes made hereafter to such terms by law or regulation.
 - a. "HIPAA" means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.
 - b. "HIPAA Regulations" means the regulations promulgated under HIPAA by the United States Department of Health and Human Services, including, but not limited to, 45 C.F.R. Part 160 and 45 C.F.R. Part 164.
 - c. "Covered Entity" means a health plan, a health care clearinghouse, or a health care provider (each as defined by HIPAA and the HIPAA Regulations) that transmits any health information in electronic form in connection with a transaction covered by the HIPAA Regulations.
 - d. "Protected Health Information" or "PHI" means individually identifiable health information, except that Protected Health Information excludes individually identifiable health information in education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. §1232g, records described at 20 U.S.C. §1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.
2. **Obligations of Covered Entity.**
 - a. *Data Set.* Covered Entity agrees to share the following data with Data User: [insert description, or include as an attachment]_____ (the "Data Set").

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Such Data Set shall not contain any of the following identifiers of the individual(s) who is(are) the subject(s) of the Protected Health Information, or of relatives, employers or household members of the individual(s): names; postal address information, other than town or city, state and zip code; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.

3. Obligations of Data User.

- a. *Performance of Activities.* Data User may use and disclose the Data Set received from Covered Entity only in connection with the performance of the following research activities: Completion of the Specific Aims of the TED initiative and any adjunct research activities generated by the TED initiative.
- b. *Assurances of Data User's Non-Employee Agents.* Data User shall not disclose the Data Set to any non-employee agent, or subcontractor of Data User except with the express prior written consent of Covered Entity. Data User shall ensure that any agents, including subcontractors, to whom it provides the Data Set agree in writing to be bound by the same restrictions and conditions that apply to Data User with respect to such Data Set.
- c. *Nondisclosure Except As Provided In Agreement.* Data User shall not use or further disclose the Data Set except as permitted or required by this Agreement or as otherwise required by law.
- d. *Safeguards.* Data User shall use appropriate safeguards to prevent use or disclosure of the Data Set other than as provided by this Agreement.
- e. *Reporting.* Data User shall report to Covered Entity within twenty-four (24) hours of Data User becoming aware of any use or disclosure of the Data Set in violation of this Agreement or applicable law.
- f. *Identification and Contacting of Individuals.* Data User shall not identify the information or contact the individuals included in the Data Set.

4. Material Breach, Enforcement and Termination.

- a. *Term.* This Agreement shall be effective as of the Agreement Effective Date and shall continue until the Agreement is terminated by the parties or in accordance with the provisions of this Section 4. All of Data User's confidentiality obligations herein shall survive the expiration or termination of this Agreement indefinitely.
- b. *Covered Entity's Rights of Access and Inspection.* From time to time upon reasonable notice, or upon a reasonable determination by Covered Entity that Data User has breached this Agreement, Covered Entity may inspect the facilities, systems, books and records of Data User to monitor compliance with this Agreement. The fact that Covered Entity inspects, or fails to inspect, or has the right to inspect, Data User's facilities, systems and procedures does not relieve Data User of its responsibility to comply with this Agreement, nor does Covered Entity's (1) failure to detect or (2) detection of, but failure to notify Data User or require Data User's remediation of, any unsatisfactory practices constitute acceptance of such practice or a waiver of Covered Entity's



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enforcement or termination rights under this Agreement. The parties' respective rights and obligations under this Section 4.b. shall survive termination of the Agreement.

- c. *Indemnification.* Data User shall indemnify, hold harmless and defend Covered Entity from and against any and all claims, losses, liabilities, costs and other expenses resulting from, or relating to, the acts or omissions of Data User in connection with the representations, duties and obligations of Data User under this Agreement. Covered Entity shall likewise indemnify, hold harmless and defend Data User from any and all claims, losses, liabilities, costs and other expenses resulting from, or relating to, the acts or omissions in connection with the representations, duties and obligations of any party including but not limited to the Repository. UCSF will not be liable for any claims, losses, liabilities, costs and other expenses or damages, including but not limited to data breaches not caused by the gross negligence of UCSF. The parties' respective rights and obligations under this Section 4.f. shall survive termination of the Agreement.

5. Miscellaneous Terms.

- a. *Governing Law.* Parties agree to remain silent on choice of law.
- b. *Amendment.* Covered Entity and Data User agree that amendment of this Agreement may be required to ensure that Covered Entity and Data User comply with changes in state and federal laws and regulations relating to the privacy, security, and confidentiality of PHI or the Limited Data Set.
- c. *No Third-Party Beneficiaries.* Nothing express or implied in this Agreement is intended or shall be deemed to confer upon any person other than Covered Entity and Data User, and their respective successors and assigns, any rights, obligations, remedies or liabilities.
- d. *Order of Precedence.* To the extent that any provisions of this Agreement conflict with the provisions of any other agreement or understanding between the parties with respect to use of the Data Set provided hereunder, this Agreement shall control.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the dates set forth below.

**THE REGENTS OF THE UNIVERSITY OF
CALIFORNIA, ON BEHALF OF ITS
SAN FRANCISCO CAMPUS**

[DATA CONTRIBUTOR]

Signature: _____

Signature: _____

Printed Name: _____

Printed Name: _____

Title: _____

Title: _____

Date: _____

Date: _____