TBI Model Systems National Database
External Use Request and Data Use Agreement Form

Note: This form is for requesting use of the national database by the general scientific community.

Purpose of use (check all that apply):

___ Research

___ Other (specify): _____

Principal investigator's name:

Principal investigator's position:

Principal investigator's institution(s) (check one):

___Non-profit organization

___For-profit organization

___Government agency

___ Other (specify): _____

Principal investigator's address:

Principal investigator's e-mail:

Collaborators' names (after each name, please include the collaborator's affiliated center(s) or organization(s) in parentheses):

Today's date:

Project start date:

Projected completion date:

Date request last updated:

Proposed Research:

Below please give a brief summary (no more than 4 pages) of the proposed work to be completed with these data. Please follow the format indicated below.

Title of project:

Key words:

Background/Introduction:

Study aim(s):

Research hypotheses:

Methods:

    Study sample:

    Primary outcome measures:

    Secondary outcome measures:

    Covariates/confounding measures:

    Data analysis plan:

    Sample size calculation:

Are you requesting any TBIMS NDB archived variables? If so, please list:

    __ Yes: _____

    __ No

[For a list of archived variables go to tbindsc.org and click on the Data Dictionary tab at left; then click on the Data Dictionary button, which brings up the Data Dictionary Explorer. Under the search function, click *Yes* for include ARCHIVED variables; then click the green search button. Under each domain, subdomain or variable, it will indicate if it has been archived.]

Do you intend to link the TBIMS NDB with any other datasets; for example, with any of the geographic identifier variables listed below?

___ Yes

___ No

If so, please describe the data to be linked to the TBIMS National Database and the linking procedures/techniques to be used:

With this request, you will receive a de-identified dataset. However, if you require any variables in the limited dataset for the specific purpose of your study, you must indicate below the variables required and the justification of why the variables are needed for the purposes of your study:

___ StateCode

___ CountyCode

___ CensusTract

___ CensusBlock

___ Zip Code

    ___ ZipInj (zip code at injury)

    ___ ZipDis (zip code at discharge)

    ___ ZipF (zip code at follow-up)

___ The full date of any date variable (e.g., date of injury, date of birth)

    Please indicate which dates: _____

IRB approval numbers and expiration dates (not necessary for initial submission, but required prior to release of the data):

Dissemination Plan:

__ Publication

__ Presentation

__ Other (specify): _____

In what format would you like the data?

__ SAS

__ SPSS

__ CSV

TBIMS External Data Use Agreement

This Data Use Agreement (the "Agreement") is effective as of [month, day, year] (the "Agreement Effective Date") until [month, day, year] (the "Agreement Termination Date", which will be three (3) years from data release) by and between the Traumatic Brain Injury Model Systems National Data and Statistical Center at **Craig Hospital** ("Covered Entity") and **[name of Data User]** ("Data User").

In 1987, the US Department of Education, National Institute on Disability and Rehabilitation Research (NIDRR), funded the Traumatic Brain Injury Model Systems (TBIMS) Program. The program is currently funded through the Department of Health and Human Services, National Institute of Disability, Independent Living and Rehabilitation Research (NIDILRR – formerly NIDRR). One of the major components of the TBIMS program is a standardized National Database (NDB) for innovative collection, processing, storage and analyses of data relevant to traumatic brain injury (TBI) treatment and outcomes. The TBIMS NDB contains information on cases treated within any TBIMS center funded since 1987, which are located around the United States. Over the years, variables have been added and deleted from the TBIMS NDB. When a variable is deleted, the data collected for this variable is archived and is available by request.

The TBIMS National Data and Statistical Center (TBINDSC) located at Craig Hospital in Englewood, Colorado, is a central resource for researchers and data collectors within the TBIMS program. The primary purpose of the TBINDSC is to advance medical rehabilitation by increasing the rigor and efficiency of scientific efforts to longitudinally assess the experience of individuals with TBI. The TBINDSC provides technical assistance, training, and methodological consultation to 16 TBIMS centers as they collect and analyze longitudinal data from people with TBI in their communities, and as they conduct research toward evidence-based TBI rehabilitation interventions. The TBINDSC (also funded by NIDILRR) houses and manages the TBIMS NDB. This data use agreement is used to allow release of the TBIMS NDB from the TBINDSC to any of the currently funded TBIMS Centers.

For External Requests for the TBIMS NDB, requestors will receive a de-identified dataset. However, if requestors require any variables in the limited dataset for the specific purpose of their study, they must indicate on *DS201F – External Data Request Form and DUA* the variables required and the justification of why the variables are needed for the purposes of their study. If the requestor is a Data User's Agent, the requestor will receive the data from the PI on the study after the latter has received this signed Data Use Agreement and written consent from the Covered Entity.

RECITALS

WHEREAS, the TBIMS National Data and Statistical Center as Covered Entity possesses *Individually Identifiable Health Information* that is protected under the **Health Insurance Portability** and Accountability Act of 1996 (HIPAA) (as hereinafter defined) and the HIPAA Regulations (as hereinafter defined), and is permitted to use or disclose such information only in accordance with HIPAA and HIPAA Regulations;

WHEREAS, Data User performs certain Activities (as hereinafter defined);

WHEREAS, Covered Entity wishes to disclose a Limited Data Set (as hereinafter defined) to Data User for use by Data User in performance of the Activities (as hereinafter defined);

WHEREAS, Covered Entity wishes to ensure that Data User will appropriately safeguard the Limited Data Set in accordance with HIPAA and the HIPAA Regulations; *and*

WHEREAS, Data User agrees to protect the privacy of the Limited Data Set in accordance with the terms and conditions of this Agreement, HIPAA and the HIPAA Regulations;

NOW THEREFORE, Covered Entity and Data User agree as follows:

1. **Definitions** The parties agree that the following terms, when used in this Agreement, shall have the following meanings, provided that the terms set forth below shall be deemed to be modified to reflect any changes made to such terms from time to time as provided in HIPAA and the HIPAA Regulations.
    a. *Activities* shall mean tasks and actions related to the performance of TBI Model System research projects.
    b. *Covered Entity* means a health plan (as defined by HIPAA and the HIPAA Regulations); a health care clearinghouse (as defined by HIPAA and the HIPAA Regulations); or a health care provider (as defined by HIPAA and the HIPAA Regulations) who transmits any health information in electronic form in connection with a transaction covered by the HIPAA Regulations.
    c. *HIPAA* means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.
    d. *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.
    e. *Individually Identifiable Health Information* means information that is a subset of health information, including demographic information collected from an individual, and;
        i. is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
        ii. relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and
            1) that identifies the individual; or
            2) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.
    f. *Limited Data Set* shall have the same meaning as the term "limited data set" in 45 CFR 164.514(e) of the Privacy Rule. A limited data set is Protected Health

Information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: 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), full face photographic images, and any comparable images.

g. *Privacy Rule* shall mean the Standards for Privacy of Individually Identifiable Information at 45 CFR Part 160 and Part 164, Subparts A and E, as amended from time to time.

h. *Protected Health Information* or *PHI* means Individually Identifiable Health Information, excluding certain education and employment records in accordance with the HIPAA regulations, that is transmitted by electronic media; maintained in any medium described in the definition of the term electronic media in the HIPAA Regulations; or transmitted or maintained in any other form or medium.

i. *Required by Law* shall have the same meaning as the term "required by law" in 45 CFR Sect. 164.501 of the Privacy Rule.

2. **Obligations of Covered Entity**

   a. *Limited Data Set*. Covered Entity agrees to disclose the following Protected Health Information to Data User: The Traumatic Brain Injury Model Systems (TBIMS) National Database (NDB) (*a "Limited Data Set"* as defined herein). Such Limited Data Set shall not contain any identifiers of the individual who is the subject of the Protected Health Information, or of relatives, employers or household members of the individual as listed above in section 1f.

   b. *PHI not allowed in limited datasets that is retained by the TBINDSC*. The TBINDSC does retain PHI not allowed in the limited datasets (e.g., street addresses and latitude/longitude coordinates). These data are not available to any internal (TBIMS) or external Data User. These data are only released by the TBINDSC to vendors under a Business Associates Agreement (BAA) for the sole purpose of converting addresses to latitude/longitude coordinates, census tracts, and other geocode information (e.g., distance to particular facilities).

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 TBI Model System research activities. Data User shall limit the use or receipt of the Data Set to members of the Traumatic Brain Injury Model Systems research team at **[name of institution where research is being conducted]**.

   b. *Nondisclosure Except as Provided in Agreement*. Data User shall not use or further disclose the Limited Data Set except as permitted or required by this Agreement.

    i.   Specifically, there is no redistribution or sharing of the TBIMS NDB with anyone or any entity for any reason, except that required for journal publication or by research funding agencies. In which case, the Data User must notify the TBINDSC in writing, and any PHI must be removed prior to redistribution/sharing for this purpose.

    ii. **Specifically, use of TBIMS data is restricted to the purpose stated in the request and only for a period of two (2) years from the date of data receipt. New or further use of data requires a new request and Data Use Agreement. Data will not be further analyzed and new results will not be shared/presented/submitted for publication under an expired notification.**

c. *Use or Disclosure as if Covered Entity*. Data User may not use or disclose the Limited Data Set in any manner that would violate the requirements of HIPAA or the HIPAA Regulations if used or disclosed by Covered Entity.

d. *Linking of Limited Data Set*. Linking of the TBIMS NDB data to any other data is prohibited without the explicit description of the data to be linked and the linking procedures to be used in the request for TBIMS NDB data.

    i.   Data Users linking other data to the TBIMS NDB data will provide the TBINDSC with information regarding the success of their linking (the description and number of cases linked and the procedures employed) and information on how other researchers can request the linked variables.

    ii. If allowed by the source of the data linked to the TBIMS NDB cases, the data linked to TBIMS cases may be redistributed by the original requestor along with the TBIMS NDB variables Mod1Id (a unique case ID assigned by the TBINDSC for Form 1 variables) and Mod2Id (a unique case ID assigned by the TBINDSC for Form 2 variables), but not any other TBIMS NDB data. [This is intended to prohibit the redistribution of the TBIMS NDB data, while still allowing others to re-link the non-TBIMS NDB data to TBIMS NDB data based on the Mod1Id and Mod2Id stored and distributed as a part of the non-TBIMS NDB data.]

    iii. By signing this Data Use Agreement, Data Users acknowledge the responsibilities associated with linking data to the TBIMS NDB, if applicable.

e. *Identification of Individual*. Data User may not use the Limited Data Set to identify or contact any individual who is the subject of the PHI from which the Limited Data Set was created.

f. *Disclosures Required by Law*. Data User may use and disclose the Limited Data Set as required by law. Data User shall advise Covered Entity, in writing, prior to any such disclosure, so that the Covered Entity shall have the opportunity to object or otherwise respond to such disclosure. A number of TBIMS centers have a Certificate of Confidentiality that covers disclosure of their data; therefore, Data User must treat all data as being covered by a Certificate of Confidentiality until advised otherwise by Covered Entity.

g. *Safeguards*. Data User shall use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided by this Agreement.
   i. Specifically, Data Users provided with any PHI allowed in limited datasets (with specific justification), are to maintain strict security of PHI, personally supervise its use, and delete the PHI as soon as possible, and signing this Data Use Agreement acknowledges those responsibilities.
h. *Data User's Agent*. Data User shall not disclose the Limited Data Set to any agent or subcontractor of Data User except with the prior written consent of Covered Entity. Data User shall ensure that any agents, including subcontractors, to whom it provides that Limited Data Set agree in writing to be bound by the same restrictions and conditions that apply to Data User with respect to such Limited Data Set.
   i. Anyone receiving the NDB data, including any Data User's Agent will need to complete a data use agreement. Any external collaborator listed on the notification who receives the NDB data must sign *DS201F – External Data Request Form and DUA*.
i. *Reporting*. Data User shall notify Covered Entity within 48 hours of Data User becoming aware of any use or disclosure of the Limited Data Set in violation of this Agreement or applicable law.
   i. Specifically, Data Users are prohibited from attempting to use the TBIMS NDB data to identify TBIMS participants, and any inadvertent identification is to be reported to the TBINDSC.
   ii. **Data Users will provide annual updates to the TBINDSC on the progress of their project, including any dissemination (e.g., digital or hard copy abstracts, presentations, publications, or any other products.)**
j. *Dissemination of Study Findings.*
   i. Data Users will include the following citation for the TBIMS National Database in any dissemination of the study findings including all digital or hard copy manuscripts, posters, presentations, and other products:
      1) Title: Traumatic Brain Injury Model Systems National Database
      2) Author: Traumatic Brain Injury Model Systems Centers Program
      3) Distributor: Traumatic Brain Injury Model Systems National Data and Statistical Center
      4) Persistent identifier: DOI 10.17605/OSF.IO/A4XZB
      5) Date: _____ [insert year of data release]
      6) url: http://www.tbindsc.org
      7) Version: https://osf.io/a4xzb/
   ii. Data Users will include the following acknowledgement in any dissemination of study findings including all digital or hard copy manuscripts, posters, presentations, and other products:

      "This (insert type of publication; e.g., book, report, film) used the Traumatic Brain Injury Model Systems National Database, which

is supported by funding from the National Institute on Disability, Independent Living, and Rehabilitation Research. NIDILRR is a Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of this (insert type of publication; e.g., book, report, film) do not necessarily represent the policy of NIDILRR, ACL, or HHS, and you should not assume endorsement by the Federal Government."

    iii. Data Users will provide the TBINDSC the URL and complete citation for any publication (written or electronic) of research using the TBIMS NDB.

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 Termination Date or in accordance with the provisions of Section 4.c.

    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 may have breached this Agreement, Data User shall make available for Covered Entity's review and inspection Data User's internal practices, systems, books and records so that Covered Entity may determine Data User's compliance with its obligations under this Agreement. The fact that Covered Entity inspects, or fails to inspect, or has the right to inspect Data User's 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 enforcement or termination rights or waiver of Data User's obligations under this Section 4.b. This Section 4.b. shall survive termination of the Agreement.

    c. *Termination*. Covered Entity may terminate this Agreement:

        i. immediately if Data User is named as a defendant in a criminal proceeding for a violation of HIPAA or the HIPAA Regulations;

        ii. immediately if there is a finding or stipulation that the Data User has violated one of the following:

            1) any standard or requirement of HIPAA or the HIPAA Regulations; or

            2) any other security or privacy laws as determined or stipulated in an administrative or civil proceeding in which Data User has been joined; or

            3) pursuant to Sections 4.d.iii. or 5.b. of this Agreement.

    d. *Remedies*. If Covered Entity determines that Data User has materially breached or violated a material term of this Agreement, Covered Entity may, at its option, pursue any and all of the following remedies:

        i. exercise any of its rights of access and inspection under Section 4.b. of this Agreement;

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any other reasonable steps that Covered Entity, in its sole discretion, shall deem necessary to cure such breach or end such violation; and/or
terminate this Agreement immediately.

e. *Knowledge of Non-Compliance*. Any non-compliance by Data User with this Agreement or with HIPAA or the HIPAA Regulations automatically will be considered a material breach or violation of a material term of this Agreement if Data User knew or reasonably should have known of such non-compliance and failed to take reasonable steps immediately to cure the non-compliance.

f. *Reporting to United States Department of Health and Human Services*. If Covered Entity's efforts to cure any material breach or end any material violation are unsuccessful as determined in the sole discretion of Covered Entity, and if termination of this Agreement is not feasible, Covered Entity shall report Data User's material breach or material violation to the Secretary of the United States Department of Health and Human Services. Covered Entity shall advise Data User that Covered Entity has made such a report to the United States Department of Health and Human Services and Data User agrees that it shall not have or make any claim(s) whether at law, in equity, or under this Agreement, against Covered Entity with respect to such reports(s).

g. *Disposition of Records*. Upon termination of this Agreement, Data User may retain the Limited Data Set but may only use and disclose the Limited Data Set for the purposes specified in this Agreement and only in accordance with the terms of this Agreement (unless said termination is due to a HIPAA violation, in which case the Limited Data Set must be returned to Covered Entity or destroyed in accordance with HIPAA regulations). However, Data User must abide by institutional protocols that may require destruction of data after Data Use Agreement expiration. This section shall survive termination of this Agreement.

h. *Injunctions*. Covered Entity and Data User agree that material violations of the provisions of this Agreement may cause irreparable harm to Covered Entity. Accordingly, in addition to any other remedies available to Covered Entity at law, in equity, or under this Agreement, in the event of any material breach or violation of any of the provisions of this Agreement by Data User, or any explicit threat thereof, Covered Entity shall be entitled to an injunction or other decree of specific performance with respect to such violation or explicit threat thereof without the necessity of demonstrating actual damages. The parties' respective rights and obligations under this Section 4.h. shall survive termination of the Agreement.

i. *Indemnification.* Data User shall indemnify, hold harmless and defend Covered Entity from and against any and all claims, losses, liabilities, costs and other expenses to the extent resulting from the negligence, recklessness, or intentional misconduct of Data User, including without limitation, the negligent, reckless or intentional acts or omissions of Data User in connection with the representations, duties and obligations of Data User under this Agreement. Covered Entity shall indemnify, hold harmless and defend Data User from and against any and all

claims, losses, liabilities, costs and other expenses to the extent resulting from the negligence, recklessness, or intentional misconduct of Covered Entity, including without limitation, the negligent, reckless or intentional acts or omissions of Covered Entity in connection with the representations, duties and obligations of Covered Entity under this Agreement. The parties' respective rights and obligations under this Section 4.i. shall survive termination of the Agreement.

5. **Miscellaneous Terms**
   a. *State Law*. Nothing in this Agreement shall be construed to require Data User to use or disclose the Limited Data Set without a written authorization from the individual who is the subject of the PHI from which the Limited Data Set was created; or written authorization from any other person, where such authorization is required under state law for such use or disclosure.
   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. Covered Entity may terminate this Agreement upon 30 days written notice in the event that the Covered Entity and Data User cannot agree upon such an amendment that ensures that Covered Entity and Data User will be in compliance with such laws and regulations within that timeframe. Whether Covered Entity or Data User agrees upon such an amendment is within the sole discretion of each party hereto.
   c. *No Third-Party Beneficiaries*. Nothing expressed 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. *Ambiguities*. The parties agree that any ambiguity in this Agreement shall be resolved in favor or a meaning that complies and is consistent with applicable law protecting the privacy, security and confidentiality of PHI and the Limited Data Set, including, but not limited to, HIPAA and the HIPAA Regulations.
   e. *Primacy*. To the extent that any provisions of this Agreement conflict with the provisions of any other agreement or understanding between the parties, this Agreement shall control with respect to the subject matter of this Agreement.
   f. *Surviving Provisions in the Event of Termination.* In the event of termination of this Agreement, only those provisions that have been identified herein to survive termination, and specifically the obligations of Data User under Section 3, shall remain in effect after such termination.
   g. *Notices*. All notices, demands, and other communications hereunder, except exchanges of technical information and invoices for services rendered, shall be delivered personally to the party hereto which it is addressed or mailed to such party by registered or certified mail, return receipt requested, with postage hereon fully prepaid at the following addresses, unless otherwise subsequently modified by change of address in writing:

   If to Data User: ==Data User== _____

Name _____
Title _____
Address _____

With a copy to:

Name _____
Title _____
Address _____

If to TBINDSC:

The Project Director, TBINDSC
Craig Hospital
3425 S Clarkson St
Englewood, CO 80113

Any notices, demands, and other communications delivered personally shall be deemed to have been received by addressee at the time and date of its delivery. Any notices, demands, and other communications so mailed shall be deemed to have been received by the addressee seven (7) days after the time and date of its being mailed.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the Agreement Effective Date.

Traumatic Brain Injury Model Systems   **[name of Data User]**
National Data and Statistical Center
At Craig Hospital

_____   _____

Project Director   **[Name of Data User]**
Traumatic Brain Injury Model Systems   **[Title of Data User]**
National Data and Statistical Center
Craig Hospital