



**TBI Model Systems National Database
and Archived Collaborative Module Study Databases
Public Use Request and Data Use Agreement Form**

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

Purpose of use (check all that apply):

- Research
- Other (specify): _____

Dataset to be used (check all that apply):

- National Database
- Archived Module database
- (specify): _____

Principal investigator's name:

Principal investigator's position:

Principal investigator's institution (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 or organization in parentheses):

Today's date:

Project start date:

Projected completion date:

Date 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:



Traumatic Brain Injury Model Systems National Data and Statistical Center STANDARDIZED OPERATING PROCEDURE 602df

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:

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):

Data Use Agreement

I (the PI named above) request access to the TBI Model Systems Data that is collected and maintained by the Traumatic Brain Injury Model Systems (TBIMS) for the purpose specified above and agree to the following terms:

1. I will receive access to de-identified data and will not attempt to establish the identity of, or attempt to contact, any of the subjects from whom these data were collected.
2. I will not further disclose these data beyond the uses outlined in this agreement and in my data request described above in this application.
3. I will promptly notify the TBI Model Systems National Data and Statistical Center of any substantive changes to the proposed research project or of any new projects to be initiated with the requested data. Such notification will consist of a new project description (i.e., the submission of a new Public Use Request and Data Use Agreement Form).
4. I will require anyone on my team who utilizes these data to comply with this data use agreement.
5. I will provide annual updates on the progress of this project.
6. I will comply with any rules and regulations imposed by my institution and its Institutional Review Board in requesting and using these data.



Traumatic Brain Injury Model Systems National Data and Statistical Center STANDARDIZED OPERATING PROCEDURE 602df

- 7. I agree that the use of the data for this request is limited to two years and after such time a new Public Use Request and Data Use Agreement Form should be sent to the TBI Model Systems National Data and Statistical Center for re-approval.
- 8. I will report any use or disclosure of the data not provided for by this Agreement of which I become aware within 15 days of becoming aware of such use or disclosure.

If I publish abstracts or papers using data from the TBI Model Systems, I agree to the following:

- 1. I will describe the methods of data gathering used for the TBI Model Systems data.
- 2. I will add the following acknowledgement to the published product:

“The TBI Model Systems National Database [or the “name the module study database”] is supported by the U.S. Department of Education, National Institute on Disability and Rehabilitation Research (NIDRR) in collaboration with the TBI Model Systems Centers.. However, these contents do not necessarily reflect the opinions or views of the TBI Model Systems Centers, NIDRR or the U.S. Department of Education.”
- 3. I will submit manuscripts to the TBI Model Systems National Data and Statistical Center for administrative review 4 weeks prior to submission elsewhere. This review is not intended to be scientific, but rather administrative to ensure that the terms of this user agreement have been fulfilled and that the data collection methods for the TBI Models Systems Centers have been accurately described. The TBI Model Systems National Data and Statistical Center and the Research Committee will maintain confidentiality of manuscripts, abstracts, and presentations
- 4. I will apprise the TBI Model Systems National Data and Statistical Center of acceptance or rejection of manuscripts.
- 5. I will provide manuscript, abstract, and presentation citations to the TBI Model Systems National Data and Statistical Center upon acceptance.
- 6. I will provide the URL and complete citation for any published manuscript, abstract or presentation using the TBI Model Systems data to the TBI Model Systems National Data and Statistical Center when available.

I understand that failure to abide by these guidelines will result in termination of my current and future privileges to access the TBI Model Systems Data. Should I try to publish Traumatic Brain Injury Model System data fraudulently or breach this data use agreement, immediate steps will be taken to secure the breach or end the violation. This may include discontinuing the user’s data access and/or reporting the violation, and reporting scientific misconduct to the violator’s institution and/or relevant professional organizations and or scientific institutions.

_____PI Signature _____Date