

DS001 Access to the TBIMS National Database	
Review Committee: Research	Effective Date: 10/01/2019
Attachments: None	Revised Date: 6/17/2023
Forms: DSF101 - Internal Use TBIMS National Database Notification Form; DS002 – TBIMS Project Director Request for National Database Form and DUA; DSF201 - External TBIMS Data Request Form; DSF301 - Public Use Request and Terms of Use Form	Reviewed Date: 1/15/2020

Introduction:

The National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) supports the collection of data from participants in the Traumatic Brain Injury Model Systems (TBIMS) Program, a collaboration of institutions across the country collecting data for research on outcomes after a traumatic brain injury (TBI). The result of this collaboration is a unique well-characterized population of subjects with uniformly collected data. The TBIMS Centers Program has a responsibility to the public in general, and to the scientific community in particular, to encourage scientific use of the TBIMS National Database (NDB) as rapidly as possible, subject to appropriate terms and conditions. This document outlines the policies for data access, use, and publication/presentation for those who desire to use the TBIMS NDB.

Purpose:

To define the process by which the scientific community and the general public can gain access to the TBIMS NDB.

Scope:

- 1) All staff, students, and other related personnel involved in the NIDILRR-funded TBIMS Centers who wish to use data from the TBIMS NDB;
- 2) Previously funded TBIMS Centers that are currently funded as TBIMS Longitudinal Follow-Up Centers;
- 3) Non-TBIMS entities that have been designated as formal collaborators per SOP DS004 *Policy and Procedure for Collaborative Relationships between TBIMS and Non-TBIMS Entities*;
- 4) All staff, students, and other related personnel at an institution that has a NIDILRR-funded TBIMS Center or Follow-up Center, but not involved in the TBIMS Center or Follow-up Center at that institution who wish to use data from the TBIMS NDB; this would include previously funded TBIMS Centers that are no longer funded and no longer collecting follow-up data; and

- 5) The scientific community at large and the general public.

Responsibilities:

All TBIMS, TBIMS Follow-up Centers, the TBIMS National Data and Statistical Center (NDSC), the larger scientific community, and the general public will abide by this procedure.

Procedural steps:

Procedure for Internal Requests:

This section addresses the use of the TBIMS NDB by TBIMS users (defined as #1, #2 and #3 under Scope above).

Policy

The TBIMS are committed to encouraging the productive and scientifically responsible use of the TBIMS NDB in a timely and effective manner to answer appropriate research questions. The policy includes the following requirements:

- 1) An analysis may be proposed through the Notification listserv by a funded TBIMS Center, a TBIMS Longitudinal Follow-up Center, or a Non-TBIMS entity that has been designated as a formal collaborator per SOP 604a. Non-TBIMS entities that do not have the designation of formal collaborators may collaborate on proposed projects at the invitation of the lead investigator (from a TBIMS Center, a TBIMS Longitudinal Center or an entity with a formal collaboration). The procedure detailed below is designed primarily for notification purposes and to allow other Centers to collaborate if desired or needed. It is not necessary to solicit additional Centers beyond three to collaborate on the project.
- 2) When there are fewer than three collaborating Centers, the process is designed to solicit additional collaborators to promote an equitable representation of the Centers contributing to the TBIMS NDB. However, all collaborators must intend and be able to play a substantial role in creating the end product, contributing skills, knowledge and/or insights that complement those of the original proposer(s).
- 3) When a lead investigator or co-investigator on a proposed project leaves the original institution, he or she may continue involvement in the project, at the discretion of the TBIMS Project Director(s) of the lead site, and assuming sufficient funding and resources are available to complete the project.
- 4) The posting of an updated notification after the process of scrutiny of the idea for duplication of other efforts gives the proposer and his/her team of collaborators a **three-year term** during which they can work to perform the analysis and reporting proposed. While a major purpose of the Notification listserv is to ensure that others within and outside the TBIMS are not allowed to propose or perform analyses that are considered largely overlapping, this cannot be assured since the TBIMS Public Use Dataset and TBIMS data stored in the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system can be accessed without using the Notification listserv, although users are encouraged to do so.
- 5) Anyone receiving the NDB data will need to complete a data use agreement. Internal collaborators, whether PI or other internal researcher, who receive NDB data must abide

by the terms of DSF101 - Internal Use TBIMS National Database Notification Form and DUA and/or DS002 - TBIMS Project Director Request for National Database. Any external collaborator listed on the notification who receives the NDB data must sign DSF201 - External Data Request Form and DUA.

Notification Process

- 1) As early as possible in the research process, the Principal Investigator (PI) must send an email notification of the project to the TBIMS Notification Listserv at tbimsnoti@lists.service.ohio-state.edu. The email must include a completed and signed DSF101 - Internal Use TBIMS NDB Notification Form and DUA.
- 2) The notification must occur as early as possible in the research process in order to facilitate involvement by interested collaborators and to allow for a check for duplication of projects. This should occur at the time of the initial planning process when an idea and methodology are being generated and before actual analyses are performed.

Collaboration

- 1) Other Centers that are interested in collaborating on the project have 10 working days in which to contact the PI and express the desire to collaborate. **Those wishing to participate must suggest meaningful input they could offer to the project.** This policy encourages collaboration, while acknowledging projects must be manageable. While every TBIMS investigator has a stake in using the TBIMS NDB they have helped collect and likely has value to contribute to a specific project, there are limited opportunities on a manuscript for substantial contribution to conception, design, analysis, interpretation, and writing. Anyone volunteering to collaborate should critically consider her/his potential contributions and intent to follow through. People offering collaboration should provide very *specific* information about the additional expertise they offer and the roles they are willing to serve on the project. The PI can facilitate this process by specifying gaps that may remain in the study team (e.g., expertise or specific roles). **The PI has the right to accept or decline the participation of interested researchers based on her/his judgment as to whether the contributions of each will meet the needs of the project and will not be duplicative of skills and other resources already in place.** It will be the responsibility of the proposing center and the other interested parties to work out a satisfactory arrangement. If such an arrangement cannot be made, the matter must be referred to the Chair of the TBIMS Research Committee who will then take the issue to the Committee for resolution. However, it is assumed that reasonable efforts will be made to foster a collaboration of at least three Centers on the project, and for each researcher involved being able to contribute in such a way and extent that per the existing guidelines, he/she is entitled to authorship. PIs are encouraged to review the TBIMS authorship policy (SOP OP006 Branding and Authorship Policy) at the time of notification, early in the project development, and again at the time of manuscript preparation to encourage adherence and create opportunities, and to renegotiate authorship as needed.
- 2) If fewer than three Centers express interest and a good effort has been made to recruit the recommended number of Centers, it is permissible to move forward with the project after the 10-day notification period has ended.
- 3) It is not necessary for the PI to accept additional collaborators once three Centers are involved, if the PI deems the additional involvement unnecessary to the project. Thus, if

at any time during the 10 working day notification period, a total of three or more Centers have agreed to collaborate on the project, the project can move forward without further delay.

- 4) It is assumed that non-response by a center within 10 days indicates that the project may proceed without that center's participation or claim that the project duplicates an existing project that was properly announced through the notification process.
- 5) At the end of the 10-day notification period, the PI must post an updated notification with the updated list of collaborators to the Notification Listserv at *tbimsnoti@lists.service.ohio-state.edu*.

Notification Registry

- 1) The NDSC will maintain a list of projects submitted through the notification process and will make it available on the members' side of the NDSC website at www.tbindsc.org under "Members" and then "Notifications," which is on the left side of the page.
- 2) The PI is responsible for notifying the TBIMS NDSC of any updates to the project. Updates will need to be made at the end of the 10-day notification process and then annually, at a minimum. Annual updates must list all collaborators, and an indication of the development phase of the project as well as the titles of and other key information on any abstracts and manuscripts that have been submitted since the last update. If updates are not received by the NDSC by the anniversary of the original posting, NDSC will send out one request to supply it. If the PI is affiliated with a funded TBIMS center, the center PD will be carbon copied on this correspondence to provide additional visibility and opportunity to solicit an update. If the notification PI does not supply an update within 14 days of receiving the reminder, NDSC will refer the matter to the Research Committee. The Research Committee will review nonresponsive notifications at least twice annually. The Committee may decide to void the notification, which would make the topic area available for analysis by another group.
- 3) The NDSC will prepare a listing of all notifications including the latest update twice a year, in time for inclusion in the binder of the biannual TBIMS Project Directors' meeting. The Research Committee will review a list of expired and nonresponsive notifications at its meeting, and make decisions in accordance with this SOP to address non-reporting and/or notification expiration.
- 4) Three years after the date of data receipt of the initial updated notification, the privileges afforded by the notification system and Data Use Agreement automatically expire. Data will not be further analyzed and new results will not be shared/presented/submitted for publication under an expired notification. The original proposer has the option to submit a written request to the Research Committee Chair, at least two months before the expiration date, explaining the circumstances that prevented or will prevent achieving the original objectives within the three-year period. Upon consideration of this explanation, the Research Committee may grant a one-year extension of the approved three-year term. If the extension is not granted, the original proposer must submit a new notification in order to continue work on the project.

Duplicate Studies

- 1) If a project posted to the notification listserv bears substantial resemblance to one which was previously posted, the PI of the earlier project must notify the PI who has just posted

the new project which is perceived to be duplicative. The two PIs must attempt to come to an agreement that avoids duplication of research. Such an agreement may involve (a) the second PI and/or collaborators joining as collaborators on the first study; (b) the aims and methods of one or both studies being changed to avoid duplication if both studies proceed; or (c) the second study being discontinued as duplicative. The study that was first posted to the notification listserv must be given priority in this decision. The nature of the agreement may depend on the status of each research project at the time when the duplication is noted and the specific interests of both PIs. If a satisfactory agreement cannot be reached between the PIs, the Chair of the TBIMS Research Committee will be notified so that he/she may help resolve the issue. The Chair of the TBIMS Research Committee will assess the situation, communicate with the PIs, and consult with the full Research Committee if warranted.

Objections

- 1) Objections to the use of data as proposed in a notification must be sent by email to the originating author within 10 working days of the notification, together with a rationale and constructive suggestions for resolving duplication or partial overlap. If the matter cannot be resolved, it will be referred to the Chair of the TBIMS Research Committee who will then take the issue to the Research Committee for recommendations. This recommendation will then be forwarded to the TBIMS Project Directors for vote and resolution.

Data Sets, Publications, & Presentations

- 1) Center identity must always be treated as masked in internal reports and in publications, unless all Centers involved give written prior approval for identification of their Center.
- 2) All those who, after the initial notification or at a later time, were accepted as collaborators must be offered an opportunity to be co-authors, unless either they left the group using written notice to the PI, or repeated non-participation in meetings and other activities clearly indicates a lack of interest in further participation. In order to be included in published manuscripts, all authors must have provided meaningful input, and satisfy all other criteria for authorship specified in the standards of the American Psychological Association or the International Committee of Medical Journal Editors.
- 3) Notification must have occurred prior to submission of an abstract, presentation, or manuscript. Authors of manuscripts or abstracts submitted for presentation or publication without prior notification and all other requirements of this policy will be asked to withdraw them from review, unless their analysis is based on FITBIR or similar data available to the scientific community at large.

Studies Originating in TBIMS Committees:

- 1) All research studies utilizing the TBIMS NDB that are proposed by a TBIMS Committee must be posted through the notification process detailed above.

Grant-funded Studies Using TBIMS Data:

- 1) Studies involving the TBIMS NDB which are proposed in new TBIMS Centers' grant applications submitted to NIDILRR must follow the notification process immediately post funding notification. This applies regardless of the number of Centers involved. If

duplicate studies are posted, resolution must be sought per the procedures discussed above.

- 2) If seeking funding for a project that involves use of the TBIMS NDB from an agency or program other than the NIDILRR TBIMS Centers Program, the PI must comply with the notification process *before* submission for such funding.

Procedure for External Requests:

This section addresses the use of the TBIMS NDB by external TBIMS users (defined as #4 and #5 under Scope above).

The TBIMS Centers have made a substantial long-term contribution in establishing and maintaining the TBIMS NDB. NIDILRR and the TBIMS Centers strongly encourage appropriate collaborative relationships between outside investigators and the TBIMS investigators, and they require proper acknowledgement of the contributions of the TBIMS investigators, even if none join outside investigators on an analysis project.

It has been the expectation of both NIDILRR and the TBIMS Centers that the de-identified TBIMS NDB be made available to the general scientific community. To request the appropriate data, the requestor (i.e., the PI) must send an email to tbimsdata@craighospital.org together with a completed 602df – External TBIMS Data Request Form and DUA. The request form will contain information on the affiliation of the PI, her/his collaborators, and the research’s purpose, among other things. After receiving this request, the NDSC will work in partnership with the TBIMS Research Committee, TBIMS Project Directors, and NIDILRR TBIMS Centers Program Manager to review the request and make a judgment regarding access. The judgment will be based on the information provided and will be guided by two factors: feasibility of the proposed analysis, specifically whether the requested TBIMS NDB variables and the available data are appropriate and adequate to address the proposed research question(s); and the scientific overlap of the proposed research question(s) with existing approved proposals, both “internal” and “external.” It is anticipated that most requests will be reasonable and can be approved rapidly and that only a few will need clarification. In the rare instance that the review process leads to concern regarding the intended purpose or use of the data, the concerns will be forwarded to the NIDILRR TBIMS Centers Program Manager for a decision. Neither the NDSC nor the Research Committee will monitor IRB compliance by the requestor. However, requestors will be asked to provide IRB numbers and expiration dates on the final version of the data request and use agreement.

Requesting Data as an External User

Requestors will complete the DSF201 – External TBIMS Data Request Form and DUA. These are available for download at www.tbindsc.org on the Researchers page. These forms, once complete, can be emailed to tbimsdata@craighospital.org.

- 1) The External TBIMS Data Request Form and the External Data Use Agreement will be reviewed by the NDSC and the TBIMS Research Committee. The foci of the review are twofold: feasibility of the proposed analysis, specifically whether the requested TBIMS NDB variables and the available data are appropriate and adequate to address the proposed research question(s); and the scientific overlap with existing approved proposals, both “internal” and “external.”

- 2) Next, the NDSC will post the proposal and the recommendations from the TBIMS Research Committee to the TBIMS Notification Listserv for further comment by the TBIMS Project Directors. This is mainly to address concerns of scientific overlap and to solicit collaborators if the PI is interested in having collaborators. Note: Collaboration with TBIMS investigators is encouraged, but not required.
- 3) After the proposal has been posted to the TBIMS Notification Listserv for 10 working days, the proposal can move forward unless input from the NDSC, Research Committee, and/or Project Directors informs the Notification Lead of any concerns.
- 4) After approval, the PI will work with the NDSC to detail the proposal so that an appropriate de-identified dataset can be released to the PI.
- 5) Before releasing the dataset, the IRB approval number and expiration date must be received from the requesting institution.
- 6) Before releasing the dataset, the NDSC will delete the ID code of the contributing Centers, or, if a Center-to-Center comparison is part of the objective or Center identity is used in statistical analysis, replace the standard Center identity codes by randomly selected other codes. Analysts are not allowed to ‘unscramble’ these codes, and Center identity must always be treated as masked in any reports and in publications, unless all Centers involved give written prior approval for identification of their Center.
- 7) Use of the data for this request is limited to **two years**; after such time a new External Use Request and Data Use Agreement Form must be sent to the TBIMS NDSC for re-approval. Data will not be further analyzed, and new results will not be shared/presented/submitted for publication under an expired notification.
- 8) During the term of the project, applicants are to send annual updates to the NDSC, including the name of the PI, title of the project, progress on the project, any presentations/publication or other dissemination that has taken place, and an updated anticipated completion date.

Publication Policy

The NDSC and the TBIMS Research Committee will be charged with the administrative review of manuscripts as defined below. Neither of these parties intends to review the manuscripts for scientific quality. As part of the External TBIMS Data Request Form and TBIMS External Data Use Agreement, investigators will be asked to agree to a Publication Policy as follows:

- 1) All manuscripts will accurately describe the methods of data collection for the TBIMS NDB.
- 2) Any dissemination of the study findings including all manuscripts, posters, presentations, epubs, digital presentations, and other products must include the following citation for the TBIMS NDB:
 - a. Title: Traumatic Brain Injury Model Systems National Database
 - b. Author: Traumatic Brain Injury Model Systems Program
 - c. Distributor: Traumatic Brain Injury Model Systems National Data and Statistical Center
 - d. Persistent identifier: DOI 10.17605/OSF.IO/A4XZB
 - e. Date: ____ [insert year of dataset release]
 - f. url: <http://www.tbindsc.org>
 - g. Version: <https://osf.io/a4xzb/>

- 3) Any dissemination of the study findings including all manuscripts, posters, presentations, epubS, digital presentations, and other products must include the following acknowledgement:

“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.”

- 4) The PI will apprise the NDSC of acceptance or rejection of manuscripts, abstracts, and presentations.
- 5) The PI will provide the URL and complete citation for any published manuscript, abstract, or presentation using the TBIMS NDB to the NDSC when available.

Unusual Situations

It is expected that users of the TBIMS National Database will follow this policy and procedure and the applicable Data Use Agreement or Terms of Use Agreement.

- 1) *Failure to Follow the Data Use Agreement.* If users inadvertently violate the User Agreement, corrective action must be taken as soon as the infractions are discovered. If users willfully violate the Data Use Agreement, NIDILRR and/or the NDSC will revoke current and future access to the TBIMS NDB.
- 2) *Fraudulent Use of Data.* If the TBIMS Research Committee or the NDSC discover an attempt to publish data obtained fraudulently or become aware of any breach of the 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.

Alternative Procedures for External Requests:

There are two other mechanisms for those external to the TBIMS to access the TBIMS NDB.

The TBIMS NDB is available through the FITBIR informatics system. FITBIR was developed to share data across the entire TBI research field. Sharing data, methodologies, and associated tools, rather than just the summaries or interpretations of this information, can accelerate research progress by allowing re-analysis of data, as well as re-aggregation, integration, and rigorous comparison with other data, tools, and methods. This community-wide sharing requires common data definitions and standards, as well as comprehensive and coherent informatics approaches which have been developed by FITBIR. See the FITBIR website (<https://intbir.nih.gov/fitbir>) for complete information on FITBIR’s purpose and methodology, including access requirements.

TBIMS data submitted to FITBIR is fully de-identified. The TBIMS data submitted to FITBIR contains the Global Unique Identifier (GUID) and uses the methodology to create the GUID recommended by FITBIR. If it was not possible to assign a GUID to TBIMS cases, a Pseudo-GUID was assigned. The TBIMS data submitted to FITBIR has all variables converted to the

TBI Common Data Elements (CDEs), to the extent possible; otherwise TBIMS variables that do not map to the TBI CDEs are submitted as Unique Data Elements (UDEs). The TBIMS data submitted to FITBIR has an embargo on the usage of the most recent two years of data. The TBIMS NDB is submitted to FITBIR annually.

Public Use Dataset

It is the expectation of both NIDILRR and the TBIMS Centers that a de-identified TBIMS NDB will be made available to the general public. The differences between the Public Use Database and External Use Database are 1) the Public Use Database includes no HIPAA-defined identifiers, and 2) there is an embargo on the usage of the most recent two years of data for the Public Use Database.

To request a Public Use Database, the requestor must send an email to the email address listed on the Public Access section of the NDSC website (*tbimsdata@craighospital.org*, located at *www.tbindsc.org/Researchers.aspx* under the Public Access heading) together with a completed DSF301 - Public Use Request and Terms of Use Form. This is available for download at *www.tbindsc.org*. This form will contain information on the affiliation of the requestor and research purpose, among other things. After receiving this request, the NDSC will record the requestor’s information and will then send the Public Use Database to the requestor.

In the rare instance that there is concern regarding the intended purpose or use of the research, the concern will be forwarded to the NIDILRR TBIMS Centers Program Manager for a decision.

Grievances

Any grievances must be made to the NIDILRR TBIMS Centers Program Manager.

References:

None

History:

Date	Action
9/25/2019	Combined 602b Internal, 602d External, and added Public Use Dataset Access to create this document.
1/15/2020	Collaboration bullet #1 updated to include language regarding encouraging collaboration while keeping projects manageable, and note about PIs reviewing SOP 608 at the time of notification.
2/18/2021	Updated policy such that a DUA is required for every internal request. Deleted reference to data use that are contained in the internal data use agreement. Deleted need for NDSC for review external publications prior to journal submission. Added description of TBIMS data in FITBIR. Added clarification of public use.

Date	Action
10/7/2022	Updated policy to include information on external collaborators on internal notifications. Also revised the acknowledgement statement to the latest provided by NIDILRR.
6/16/2023	Updated policy to include information on notification expiration procedures.
6/22/2023	Removed all mention of Archived Module Datasets as a separate SOP was developed.

Review schedule:

At least every 5 years.