602f  Access to the TBIMS National Database

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<tr>
<th>Review Committee: Research</th>
<th>Effective Date: 10/01/2019</th>
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<tbody>
<tr>
<td>Attachments: None</td>
<td>Revised Date: 2/18/2021</td>
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<tr>
<td>Forms: 602bf - Internal Use TBIMS National Database Notification Form; 602a – TBIMS Internal Data Use Agreement; 602df - External TBIMS Data Request Form; 602ae – TBIMS External Data use Agreement; 602ff - Public Use Request and Terms of Use Form</td>
<td>Reviewed Date: 1/15/2020</td>
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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 and archived Collaborative Module Study Databases 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 National Database (and archived Collaborative Module Study Databases).

Purpose:
To define the process by which the scientific community and the general public can gain access to the TBIMS National Database or Archived Collaborative Module Datasets.

Scope:
1) All staff, students, and other related personnel involved in the NIDILRR-funded TBIMS Centers who wish to use data from the TBIMS National Database;
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 604a 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 National Database or Archived Modules; 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.

Procedure for Internal Requests:
This section addresses the use of the TBIMS National Database and Archived Collaborative Module Study Databases by TBI Model Systems users (defined as #1, #2 and #3 under Scope above)

Policy
The TBI Model Systems are committed to encouraging the productive and scientifically responsible use of the TBIMS National Database and Archived Collaborative Module Study Datasets 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 National Database. 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) All those using the National Data Base must abide by the terms of 602a - TBIMS Internal Data Use Agreement.

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 602bf Internal Use TBIMS National Database Notification Form, including the signed 602a - TBIMS Internal Data Use Agreement.

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 National Database 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 608 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 3 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 TBIMS National Data and Statistical Center will maintain a list of projects submitted through the notification process and will make it available on the members’ side of the NDSC web-site at www.tbimsndc.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 does not supply an update within 14 days of receiving the reminder, NDSC will refer the matter to the Research Committee. 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 meeting. The
Research Committee will review this list at its meeting, and make any decisions needed to respond to non-reporting by investigators with a valid notification.

4) Three years after the date of posting of the initial updated notification, the privileges afforded by the notification system and Data Use Agreement automatically expire, unless the original proposer submits 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.

**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 e-mail 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.

Archived Collaborative Module Study Datasets

1) Notifications of requests to use Archived Collaborative Module Study Datasets for
anything other than the originally intended analyses must be submitted using the
above procedures. Module study data will remain under the control of the lead
project team for one year after completion of data collection of the project. This
will allow ample time for analyses and preparation of planned manuscripts. After
the one-year period, any of the TBIMS Centers may request the data for
additional analysis and dissemination using the above described procedure. In
special circumstances, the lead project team may request an extension of the
one-year period if approved by the appropriate NIDILRR Project Officer and the
TBIMS Project Directors. If the NDSC receives a completed 602bf - Internal Use
TBIMS National Database Notification Form, including the 602a – Internal Data
Use Agreement, to release a Module Study Dataset prior to archiving, the NDSC
will obtain and document permission from the Module PI.

Studies Originating in TBIMS Committees:

1) All research studies utilizing the TBIMS National Database or an Archived
Collaborative Module Study Dataset 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 National Database or Archived Collaborative
Module Study Datasets 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 National Database
or Archived Collaborative Module Study Datasets 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 National Database by external TBI Model Systems users (defined as #4 and #5 under Scope above).

The TBIMS Centers have made a substantial long-term contribution in establishing and maintaining the National Database. NIDILRR and the TBIMS 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 National Database 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 602ae – TBIMS External Data Use Agreement. 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 602df – External TBIMS Data Request Form and 602ae – TBIMS External Data Use Agreement. 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 NIDILRR TBIMS Centers Program Manager will make the final decision regarding approval of the proposal, with feedback from the NDSC, Research Committee, and Project Directors.

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 ‘unsccramble” 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 TBI Model Systems National Data and Statistical Center for re-approval.

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 National Database.

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 National Database:
   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
STANDARD OPERATING PROCEDURE

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

“The TBI Model Systems National Database is a multicenter study of the TBI Model Systems Centers Program, and is supported by the National Institute on Disability, Independent Living and Rehabilitation Research (NIDILRR) a center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). However, these contents do not necessarily reflect the opinions or views of the TBI Model Systems Centers, NIDILRR, ACL or HHS.”

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 data 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 National Database.

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 National Database.

The TBIMS National Database is available through the Federal Interagency Traumatic Brain Injury Research (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 National Database is submitted to FITBIR annually.

Public Use Dataset
It is the expectation of both NIDILRR and the TBIMS Centers that a de-identified TBIMS National Database 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 602ff - 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:

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<th>Action</th>
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<tr>
<td>9/25/2019</td>
<td>Combined 602b Internal, 602d External, and added Public Use Dataset Access to create this document.</td>
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<tr>
<td>1/15/2020</td>
<td>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.</td>
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<tr>
<td>2/18/2021</td>
<td>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.</td>
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## Review schedule:

At least every 5 years.