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 not involved in the NIDILRR-funded TBIMS Centers or Follow-up Centers who wish to use data from the

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<td>Forms: 602bf - Internal Use TBIMS National Database Notification Form; 602df - External TBIMS Data Request and Use Agreement Form; 602ff - Public Use Request and Terms of Use Form</td>
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TBIMS National Database or 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 internal 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 time-efficient and effective manner to answer appropriate research questions. The policy includes the following requirements:

1) An analysis may be proposed through the Notification listserv enter, one of which must be 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. Others within and outside the TBIMS will not be allowed to propose or perform analyses that are considered largely overlapping.

5) The TBIMS NDSC and all those using the National Data Base must maintain the anonymity of both individual subjects and of Centers in all analyses and publications.

**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 that summarizes the proposed project.

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. Ideally, this occurs 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. 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.

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 a prior project.
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.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 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 indicated 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 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. The Research Committee may, upon consideration of this explanation, 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 and/or published or presented, the PI of the earlier project must notify the PI who has just posted the duplicate project. 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. 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.

4) If a TBIMS Center requests that their TBIMS National Database data be sent to another TBIMS center or a non-TBIMS entity, the NDSC will retain a copy of the request from the TBIMS Center Project Director, and will obtain a signed Data Use Agreement from the receiving center or entity, prior to sending the data. Following the notification procedure is not necessary in this situation.

5) Any **author of a publication utilizing the TBIMS National Database or an Archived Collaborative Module Study Dataset** will produce the de-identified data on which the manuscript is based for examination, if requested by an editor, reviewer, or reader of the publication. In such circumstances, review by the NDSC or the TBIMS Research Committee will not be required before such data are released.
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. 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 request to release a Module Study Dataset prior to archiving, the NDSC will obtain and document permission from the Module PI, and will obtain a signed Data Use Agreement from the receiving center or entity. Following the notification procedure is not necessary in this situation. Newly proposed Module studies that have not undergone outside peer review as part of the NIDILRR grant proposal review process must follow Standard Operating Procedure (SOP) 700g – Module Project Peer Review Procedures.

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 original TBIMS Centers’ grant applications 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.

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 data, the requestor (i.e., the PI) must send an email to tbimsdata@craighospital.org together with a completed 602df – External TBIMS Data Request and Use Agreement Form. This form will contain information on the affiliation of the PI, collaborators, and research 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 on scientific overlap with existing approved proposals. 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 and Use Agreement Form. These are available for download at www.tbindsc.org on the Researchers page. The External TBIMS Data Request and Use Agreement Form, once complete, can be emailed to tbimsdata@craighospital.org.

1) The External TBIMS Data Request and Use Agreement Form will be reviewed by the NDSC and the TBIMS Research Committee for PI’s affiliation, scientific purpose, and potential overlap with existing approved projects.

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 center, 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** and 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 analysis, applicants are to send annual updates to the NDSC, including the name of the PI, title of the project, progress on the project, 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 and 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, and other products must include the following citation for the TBIMS National Database:
   - Title: Traumatic Brain Injury Model Systems National Database.
   - Author: Traumatic Brain Injury Model Systems Program
   - Distributor: Traumatic Brain Injury Model Systems National Data and Statistical Center
   - Persistent identifier: DOI 10.17605/OSF.IO/A4XZB
   - Date: 2019
   - Url: [http://www.tbindsc.org](http://www.tbindsc.org)
   - Version: [https://osf.io/a4xzb/](https://osf.io/a4xzb/)

3) Any dissemination of the study findings including all manuscripts, posters, 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 submit manuscripts to the NDSC for administrative review at least four weeks prior to submission for publication. The NDSC will forward the manuscript submission to the TBIMS Research Committee members for review. 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 TBIMS Centers have been accurately described. The NDSC and the TBIMS Research Committee will maintain confidentiality of all manuscripts, abstracts and presentations.
5) The PI will apprise the NDSC of acceptance or rejection of manuscripts, abstracts, and presentations.

6) 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 these guidelines in good faith and that analyses will be of reasonable quality. As earlier stated, the NDSC and the TBIMS Research Committee do not intend to review abstracts or manuscripts for scientific quality. However, we do anticipate the possibility of some unusual circumstances.

1) *Egregiously Poor Manuscripts.* If a review of a proposed manuscript reveals that it is egregiously poor in terms of language, writing or sensible substance, the NDSC or the TBIMS Research Committee can recommend to the authors that it be submitted only after significant revision. In this instance, the NDSC or the TBIMS Research Committee will provide suggested changes to facilitate publication. If the authors choose to submit the manuscript without revision, the Research Committee will have two options: 1) request that the authors add a statement to the publication to the effect that while TBI Model Systems data were used, the TBI Model Systems did not find the manuscript of sufficient merit to warrant submission for publication, and; 2) revoke privileges to use TBI Model Systems data in the future.

2) *Failure to Follow the Data Use Agreement.* If users inadvertently violate the User Agreement, corrective action must be taken as soon as 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.

3) *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 Procedure for Public Requests:**

It is the expectation of both NIDILRR and the TBIMS Centers that a de-identified TBIMS National Database be made available to the general public. The differences between the Public Use Database and the previously-described 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 complete 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](http://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 concerns 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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**Review schedule:**

At least every 5 years.