Introduction:
The National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) supports the collection of data from participants in the Traumatic Brain Injury (TBI) Model Systems Program, a collaboration of institutions across the country collecting data for research on outcomes after a TBI. The result of this collaboration is a unique well-characterized population of subjects with uniformly collected data. The TBI Model Systems Centers Program has a responsibility to the public in general, and to the scientific community in particular, to encourage scientific use of the TBI Model Systems National Database.

This document outlines the policies and procedures for submitting TBI Model System (TBIMS) data to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system as one method of sharing TBIMS data with other TBI researchers. FITBIR was developed to share data across the entire TBI research field. Sharing data, methodologies, and associated tools, rather than 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.

The TBI Model Systems Centers have made a substantial long-term contribution in establishing and maintaining the National Database. NIDILRR and the TBI Model Systems encourage appropriate use of their data by other researchers. They also strongly encourage appropriate collaborative relationships between outside investigators and the TBI Model Systems investigators and they have developed longstanding procedures for external researchers requesting data directly from the TBIMS (see TBIMS Standard Operating Procedure 602d: External Use TBIMS National Database Notification). This SOP describes the commitment of the TBIMS to contribute their National Database (NDB) data to FITBIR, so that FITBIR can provide another method of facilitating access to TBIMS data by other researchers.
Purpose:
To define the process by which data in the TBI Model Systems National Database are transferred to FITBIR

Scope and Responsibilities:
The TBI National Data and Statistical Center (NDSC) implements this SOP. The TBI Model Systems Research Committee, TBI Model Systems Project Directors, and NIDILRR TBI Model Systems Centers Program Manager oversee this SOP. All TBIMS, TBIMS Follow-up Centers, NDSC, and FITBIR will abide by this procedure.

Data to be Submitted to FITBIR:
Data from the TBIMS NDB Form I (containing information through definitive discharge from inpatient rehabilitation) and Form II (containing follow-up information at 1, 2, and 5 years post injury and every 5 years thereafter) will be submitted to FITBIR. Module data will not be submitted.

Deidentification of Data:
Data submitted to FITBIR will be fully deidentified. The vast majority of TBIMS data are deidentified before entry into the TBIMS NDB stored at the TBI National Data and Statistical Center (NDSC). The NDB does not contain any names; telephone, fax, medical record, account, license, health plan, vehicle, device, or Social Security numbers; email, internet protocol, or URL addresses; or photographic, finger, or voice prints. The NDB does contain a few variables that will be deidentified before submission to FITBIR. Date of birth and date of injury will be converted to age at injury, collapsing any ages over age 89 into a single category of age 90 and over. All other dates will be converted to the number of days the date occurred after the day of injury (e.g. rehabilitation admission and discharge dates will be converted to the number of days after injury that the admission and discharge occurred; emergence from consciousness and post traumatic amnesia dates, as well as follow-up and all other dates, will be converted to days post injury. The address and zip code of residence will be converted to state of residence and the Model System that enrolled and treated the participant will be excluded from the data submitted to FITBIR.

GUID Use
When TBIMS staff recruit and consent participants, they now ask for consent to collect personal identifying information (PII) to create a Global Unique Identifier (GUID) and to submit the participant’s deidentified data to FITBIR. Participants enrolled before the adoption of this practice are asked to consent at the time of their next Form II interview. The GUID Tool is a customized software application that generates a GUID for each study participant. The GUID is a subject ID that allows researchers to share data
specific to a study participant without exposing personally identifiable information (PII). The GUID allows data from an individual who participates in multiple studies to be linked in FITBIR without identifying the individual. The GUID is made up of random alpha-numeric characters and although it is generated from PII/PHI, the GUID itself does NOT contain PII/PHI. As such, it has been approved by the NIH Office of General Counsel. GUID generation complies with HIPAA regulations for the protection of PII/PHI. The process for generating a GUID involves collecting PII, entering it into the GUID Tool (a local program), and retrieving the assigned GUID. The GUID Tool combines the PII and generates three one-way hash codes. PII cannot be extracted from these hash codes, they are strictly one-way algorithms. The one-way hash codes are sent to the GUID server. If the hash codes match the server's hash codes for an existing GUID, then that GUID is returned. If the hash codes do not match, then a new random GUID is generated and returned. The GUID process has two important attributes: 1) PII is never sent to the FITBIR system and 2) The GUID is a random number that does not reveal PII/PHI. In order to generate a GUID for a subject, the following PII is required: complete legal given name of the subject at birth (first, middle if one exists, and last), date of birth, and the city and country in which subject was born. Pseudo-GUIDs are assigned if some PII is unavailable. Pseudo-GUIDs are random alpha-numeric characters that are not associated with any hash codes generated from any PII.

**Cases to be Submitted**

Cases will be submitted to FITBIR if they have consented to the GUID and FITBIR process. Cases will not be submitted to FITBIR if they refused GUID and FITBIR participation. Cases that have not yet been asked to participate in the GUID and FITBIR process (because they were enrolled before the GUID consenting process began and they have not yet been interviewed for their next follow-up when they will be asked) will be submitted to FITBIR with a Pseudo-GUID (a random ID not generated with PII). Cases submitted with a Pseudo-GUID are completely deidentified and they have already consented to participate in the TBIMS NDB which includes data sharing. Once they have been approached and consented, their Pseudo-GUID will be replaced by their GUID. If a case submitted under a Pseudo-GUID later refuses consent, the case will be removed from FITBIR.

**Formatting of Data for Submission**

The use of variables in research which have been designated as common data elements (CDEs) facilitates the advancement of TBI research and the integration of data from multiple studies. All variables in the TBIMS NDB that are CDEs or can be logically converted to CDEs will be recoded as necessary to the coding format designated by FITBIR for CDEs. Variables which cannot be converted to CDEs will be submitted to FITBIR as unique data elements (UDEs) along with uniform data dictionary information defining the coding. The conversion of TBIMS data into CDEs and UDEs and the actual transfer of data to FITBIR will be the responsibility of the National Data
and Statistical Center (NDSC). The NDSC will follow the guidelines for data formatting and transfer established by FITBIR.

Timing of Data Submission

In order to give TBIMS researchers the first opportunity to analyze and publish results from the data they have collected, there will be a two year delay in submitting TBIMS data to FITBIR, and data will only be submitted annually. When preparing data for FITBIR submission, the NDSC will use a TBIMS dataset that was archived two years ago. For example, if the NDSC prepares a data set for submission at the end of Fiscal Year 2017, they will use the TBIMS dataset archived with all data submitted by TBIMS centers to the NDSC by the end of FY2015. The next data submission to FITBIR at the end of FY2018 would be the TBIMS data that existed at the end of FY2016. TBIMS data in FITBIR would therefore be somewhere between two and nearly three years old, depending on the time of year. The two year delay in submitting data to FITBIR is intended to be consistent with the NIDILRR policy of requiring grantees to make their data public within two years of the end of a project. NIDILRR has interpreted their policy to allow up to a two year delay in sharing data from an ongoing TBI longitudinal database. The timing described above for submitting TBIMS data to FITBIR has been described by NIDILRR as the maximum delay they would allow. External researchers wishing to access more current data can continue to use the TBIMS procedures described in SOP 602d: “External Use TBIMS National Database Notification,” which has safeguards in place for not allowing external researchers to duplicate TBIMS research already underway, but provides the most current data available to approved requests.

Access to TBIMS Data in FITBIR by Other Researchers

Once TBIMS data have been submitted to FITBIR, the data are under the control of FITBIR policies and procedures. The current routine FITBIR policy is to delay access to data in FITBIR for six months after it has been submitted, before it can be accessed by other researchers also submitting data to FITBIR. For other researchers not contributing data to FITBIR, the routine delay is one year. However, FITBIR has provisions for any investigator to request early access to data in FITBIR. That request can be granted by the submitter of the data, or in rare instances, when FITBIR overrules the submitter’s denial (on the grounds that the request does not compromise completion of the ongoing study). In the case of TBIMS data in FITBIR, to remain in compliance with NIDILRR policy on data sharing, the TBIMS will routinely grant permission to investigators requesting early access. The advantage to the TBIMS of this process is that the TBIMS will learn the identity of the researcher requesting early access and the nature of the research, thereby creating an opportunity to engage the external researcher in collaboration with TBIMS researchers who have investigations or interest in the area. The option of requesting current data directly from the TBIMS under SOP 602d: “External Use TBIMS National Database Notification” also remains available to any researcher.
Encouraging Collaboration with External Researchers

Researchers requesting TBIMS data, whether directly from the TBIMS or through FITBIR, will be encouraged but not required to collaborate with TBIMS researchers. Both methods of TBIMS data access will be described on the TBIMS NDSC website and collaboration will be encouraged. The NDSC will provide FITBIR with details of the NDB to post in order to facilitate the use of TBIMS data.

References:


History:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/1/2017</td>
<td>Posted to web site</td>
</tr>
</tbody>
</table>

Review schedule:

At least every 5 years.