Introduction:
This policy and procedure addresses the use of the Traumatic Brain Injury (TBI) Model Systems National Database and Archived Collaborative Module Study Databases by internal TBI Model Systems users.

Purpose:
To define the process by which TBI Model Systems (TBIMS) Centers, TBI Model Systems Longitudinal Follow-up Centers and Non-TBIMS Collaborating Entities (collectively referred to as “CENTERS” throughout this document) may use the TBI Model Systems National Database or an Archived Collaborative Module Dataset for publication and presentation, including the notification process to be used to inform others of one’s plan and progress.

Objective:
1) To establish procedures for assuring productive and efficient research activities using the collaborative multi-center TBI Model Systems National Database and Archived Collaborative Module Study Datasets.
2) To enhance the awareness of those associated with the CENTERS of proposed and ongoing research studies that use the national database or archived module datasets from study inception through publication of study findings.
3) To encourage and assure the appropriate level of participation by all eligible staff on projects that utilize the TBI Model Systems National Database or Archived Collaborative Module datasets.

Scope:
- Staff of the TBI Model Systems: All staff, students, and other related personnel involved in the NIDILRR-funded TBI Model Systems Centers who wish to use data from the TBI Model Systems National Database.
- Previously funded TBI Model Systems Centers that are currently funded as TBI Model Systems Longitudinal Follow-Up Centers.
Responsibilities:

All CENTERS, and the TBI Model Systems National Data and Statistical Center will abide by this procedure.

Policy:

The TBI Model Systems are committed to encouraging the productive and scientifically responsible use of the TBI Model Systems National Database and Archived Collaborative Module Study Datasets in a time-efficient and effective manner to answer appropriate research questions. These procedures were designed to specify the steps required when using the TBI Model Systems National Database or an Archived Collaborative Module Dataset.

1) An analysis may be proposed by three or more CENTERS, one of which must be a funded TBI Model Systems center or a TBI Model Systems Longitudinal Follow-up Center. Non-TBIMS entities that have been designated as formal collaborators per SOP 604a can initiate proposals and serve as lead investigators when posting proposals to the Notification Listserv. Non-TBIMS entities that do not have the designation of formal collaborators may collaborate on proposed projects at the invitation of the lead investigator. 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 should intend to 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 TBI Model Systems 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, and others within and outside the TBI Model Systems will not be allowed to propose or perform analyses that are considered largely overlapping.

5) The TBI Model Systems National Data and Statistical Center and all those using the National Database must maintain the anonymity of both individual subjects and of centers in all analyses and publications.

Procedure:

I. Notification Process:

A. As early as possible in the research process, the Principal Investigator (PI) should send an e-mail notification of the project to the TBI Model Systems Notification Listserv at “tbimsnoti@lists.service.ohio-state.edu”. The e-mail should include a completed 602bf TBI Model Systems National Database Study Notification Data Sheet (attached) that summarizes the proposed project.

B. The notification should 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 is at the time of the initial planning process when an idea and methodology are being generated and before actual analyses are performed.

II. Collaboration:

A. 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 should 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 should be referred to the Chair of the TBI Model Systems 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.

B. 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.

C. 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.

D. 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.

E. 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”.

III. **Research Registry:**
   A. The TBI Model Systems National Data and Statistical Center will maintain a list of projects submitted through the notification process and will make it available on the NDSC web-site under “Members” and then “Notifications” which is on the left side of the page.

   B. The PI is responsible for notifying the TBI Model Systems National Data and Statistical Center 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 should 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.

   C. The TBI Model Systems National Data and Statistical Center 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.

   D. 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.

IV. **Duplicate Studies:**
   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 should notify the PI who has just posted the duplicate project. The two PIs should 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 should 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 TBI Model Systems Research Committee will be notified so that he/she may help resolve the issue. The Chair of the TBI Model Systems Research Committee will assess the situation, communicate with the PIs, and consult with the full Research Committee if warranted.

V. **Objections:**
Objections to the use of data as proposed in a notification should 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 TBI Model Systems Research Committee who will then take the issue to the Research Committee for recommendations. This recommendation will then be forwarded to the TBI Model Systems Project Directors for vote and resolution.

VI. **Data Sets, Publications & Presentations:**
A. enter identity should always be treated as masked in internal reports and in publications, unless all centers involved give written prior approval for identification of their center.

B. All those who after the initial notification, or at a later time, were accepted as collaborators should be offered an opportunity to be co-authors, unless 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.

C. 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.

D. If a TBIMS Center requests that their TBIMS NDB 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.

VII. **Modules:**
Notifications of requests to use Archived Collaborative Module Study Datasets for anything other than the originally intended analyses should be submitted
using the above procedures. Research module 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 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 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 research modules that have not undergone outside peer review as part of the NIDILRR grant proposal review process should follow the Module Peer Review Policy.

VIII. Studies Originating in TBI Model Systems Committees:
All research studies utilizing the TBI Model Systems National Database or an Archived Collaborative Module Study Dataset that are proposed by a TBI Model Systems Committee must be posted through the notification process detailed above.

IX. Grant-funded studies Using TBI Model Systems Data:
Studies involving the TBI Model Systems National Database or Archived Collaborative Module Study Datasets which are proposed in original TBI Model Systems Centers’ grant applications should follow the notification process before submission. This applies regardless of the number of centers involved. If duplicate studies are posted, resolution should be sought per the procedures discussed above.

If seeking funding for a project that involves use of the TBI Model Systems National Database or Archived Collaborative Module Study Datasets from an agency or program other than the NIDILRR TBI Model Systems Centers Program, the PI must also comply with the notification process before submission for such funding.

X. Public Use
Please refer to the TBI Model Systems National Database and Archived Collaborative Module Study Public Data Sharing Policy.

Any author of a publication utilizing the TBI Model Systems 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 TBI Model Systems National Data and Statistical Center or the TBI Model Systems
Research Committee will not be required before such data are released.

**Training requirements:**
None

**Compliance:**
All TBI Model Systems users of the TBI Model Systems National Database or Archived Collaborative Module Databases must comply with this procedure.

**References:**
None

**History:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>6/10/2009</td>
<td>Transferred to SOP template</td>
</tr>
<tr>
<td>7/15/2011</td>
<td>Revised definition of type of groups that could collaborate on an internal request a dataset.</td>
</tr>
<tr>
<td>10/20/2011</td>
<td>Clarified that a center can move forward with a study even if three other centers do not express interest in collaborating as long as a good effort was made to solicit collaborators.</td>
</tr>
<tr>
<td>7/16/2013</td>
<td>Fixed the mailing address to the notification listserv</td>
</tr>
<tr>
<td>7/7/2014</td>
<td>Added: 3-year duration of exclusivity license obtained through notification; proactive process to obtain interim reports; need for broad authorship opportunities; need to maintain anonymity of patients and centers in all publications/presentations;</td>
</tr>
<tr>
<td>6/12/2015</td>
<td>Updated NIDRR to NIDILRR</td>
</tr>
<tr>
<td><strong>11/17/2016</strong></td>
<td>Added clarification of requests for a single center’s data and module data prior to archiving.</td>
</tr>
</tbody>
</table>

**Review schedule:**
At least every 5 years