

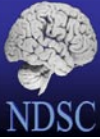
602d	External Notification Policy and Procedure for TBI Model Systems National Database Research	
Approved: TBIMS Project Directors	Effective Date:	6/10/2009
Attachments: None	Revised Date:	Transferred to SOP template 6/12/09
Forms: 602df - External Data Request and Use Agreement Form ;	Reviewed Date:	
Review Committee	SOP Committee	

Introduction:

The National Institute on Disability and Rehabilitation Research (NIDRR) has supported 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 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 for those who desire to use the TBI Model Systems National Database (and archived Collaborative Module Study Databases) and are not a funded data collection site for the TBI Model Systems, i.e. the general scientific community.

The TBI Model Systems Centers have made a substantial long-term contribution in establishing and maintaining the National Database. NIDRR and the TBI Model Systems strongly encourage appropriate collaborative relationships between outside investigators and the TBI Model Systems investigators and they require proper acknowledgement of the contributions of the TBI Model Systems investigators.

It has been the expectation of both NIDRR and the TBI Model Systems Centers that the de-identified TBI Model Systems National Database be made available to the general scientific community. To request data, the requestor [i.e., the principal investigator (PI)] should send an e-mail to the Project Director of the TBI Model Systems National Data and Statistical Center (see www.tbindsc.org and go to contacts) together with a completed 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 National Data and Statistical Center will work in partnership with the TBI Model Systems Research Committee, TBI Model Systems



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Project Directors, and NIDRR TBI Model Systems 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 research, the concerns will be forwarded to the NIDRR TBI Model Systems Centers Program Manager for a decision. Neither the National Data and Statistical Center 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.

Purpose:

To define the process by which the general scientific community can gain access to the TBI Model Systems National Database or an Archived Collaborative Module Dataset.

Scope:

All staff, students, and other related personnel not involved in the NIDRR-funded TBI Model Systems Centers or Follow-up Centers who wish to use data from the TBI Model Systems National Database or Modules. This would include previously funded TBI Model Systems Centers that are no longer funded and no longer collecting follow-up data.

Responsibilities:

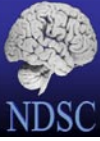
All TBIMS, TBIMS Follow-up Centers, NDSC, NIDRR and the general public will abide by this procedure.

Procedure:

Requesting data:

Requestors will complete a Data Request and Use Agreement Form. These are available for download at (www.tbindsc.org). The Data Request and Use Agreement Form, once complete, can be e-mailed or faxed to the Project Director of the TBI Model Systems National Data and Statistical Center (see www.tbindsc.org and go to contacts).

- 1) The Data Request and Use Agreement Form will be reviewed by the TBI Model Systems National Data and Statistical Center and the TBI Model Systems Research Committee for PI's affiliation, scientific purpose, and scientific overlap with existing approved projects.
- 2) Next, the TBI Model Systems National Data and Statistical Center will post the proposal and the recommendations from the TBI Model Systems Research Committee to the TBI Model Systems Notification Listserv for further comment by the TBI Model Systems 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 TBI Model Systems investigators is encouraged, but not required.



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- 3) After the proposal has been posted to the TBI Model Systems Notification Listserv for 10 working days, the NIDRR TBI Model Systems Centers Program Manager will make the final decision regarding approval of the proposal with feedback from the National Data and Statistical Center, Research Committee, and Project Directors.
- 4) After approval, the PI will work with the TBI Model Systems National Data and Statistical Center to detail the proposal so that an appropriate de-identified dataset can be released to the PI.

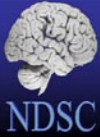
During analysis:

Applicants are to send annual updates to the TBI Model Systems National Data and Statistical Center, including the name of the PI, title of the project, progress on the project, and an updated anticipated completion date.

Publication Policy

The TBI Model Systems National Data and Statistical Center and the TBI Model Systems 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 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 TBI Model Systems National Database or archived Collaborative Module Study Databases.
- 2) Any dissemination of the study findings should include proper acknowledgement of the TBI Model Systems and NIDRR support. That is, all manuscripts, posters, and presentations will add the following acknowledgement to the published product:
“The TBI Model Systems National Database [or the “name the module study database”] was supported by the U.S. Department of Education, National Institute on Disability and Rehabilitation Research (NIDRR) in collaboration with the TBI Model Systems Centers. However, these contents do not necessarily reflect the opinions or views of the TBI Model Systems Centers, NIDRR or the U.S. Department of Education.”
- 3) The PI will submit manuscripts to the TBI Model Systems National Data and Statistical Center for administrative review at least four weeks prior to submission for publication. The National Data and Statistical Center will forward the manuscript submission to the TBI Model Systems 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 TBI Model Systems Centers have been accurately described. The National Data and Statistical Center and the TBI Model Systems Research Committee will maintain confidentiality of all manuscripts, abstracts and presentations.



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- 4) The PI will apprise the TBI Model Systems National Data and Statistical Center 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 TBI Model Systems data to the TBI Model Systems National Data and Statistical Center when available.

Unusual Situations

It is expected that users of the TBI Model Systems National Database will follow these guidelines in good faith and that analyses will be of reasonable quality. As earlier stated, the TBI Model Systems National Data and Statistical Center and the TBI Model Systems 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 TBI Model Systems National Data and Statistical Center or the TBI Model Systems Research Committee can recommend to the authors that it be submitted only after significant revision. In this instance, the TBI Model Systems National Data and Statistical Center or the TBI Model Systems 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 should be taken as soon as infractions are discovered. If users willfully violate the Data Use Agreement, NIDRR and/or the TBI Model Systems National Data and Statistical Center will revoke current and future access to the TBI Model Systems National Database.
3. **Fraudulent Use of Data.** Should the TBI Model Systems Research Committee or the TBI Model Systems National Data and Statistical Center 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.



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Grievances

Any grievances should be made to the NIDRR TBI Model Systems Centers Program Manager.

Compliance:

All non-TBIMS users of the TBIMS National Database or Archived Collaborative Module Databases must comply with this procedure.

References:

None

History:

Revised 5/12/03

Revised 6/10/09

Transferred to SOP template 6/12/09

Review schedule:

At least every 5 years.