## Introduction:
In 2008, NIDILRR and the Department of Veterans Affairs began a collaborative relationship between the TBI Model Systems (TBIMSs) and the VA Polytrauma Rehabilitation Centers. This SOP defines the parameters of that collaborative relationship.

## Purpose:
To detail a policy and procedure for a collaborative relationship between the TBIMSs and the VA PRCs.

## Scope:
All current TBIMSs, previous TBIMSs which may or may not be currently funded as a TBIMS Follow-up Center, the National Data and Statistical Center (NDSC), and the VA PRCs.

## Responsibilities:
All those specified in the scope will abide by this policy and procedure.

## Definitions:
- TBIMSs and NDSC are those that are currently designated and funded by NIDILRR as such.
- The VA PRCs are the five centers at Minneapolis, Palo Alto, Richmond, San Antonio, and Tampa.

## Procedure:
1. The VA PRCs interested in collaboration with the TBIMSs as a whole related to data collection should contact the NIDILRR TBIMS Program Manager. If the TBIMSs as a whole are interested in any type of collaboration with the VA PRCs, they should also contact the NIDILRR TBIMS Program Manager.
2. NIDILRR will determine the purpose of the collaborative relationship and determine if the agency has interest in this collaborative relationship. NIDILRR may choose to consult the TBIMS Executive Committee or its Chair in making this determination.
3. If the collaborative relationship is deemed of interest to NIDILRR, the agency will determine the level of collaboration per the descriptions detailed below.
4. The NIDILRR TBIMS Program Manager will notify the TBIMS Project Directors via the directors’ listserve and solicit/determine points of contacts (POCs) for the specific collaboration with the TBIMSs.

5. The NIDILRR TBIMS Program Manager and/or TBIMS POCs will provide updates on collaborations at semi-annual Project Directors meetings.

Due to VA data security requirements which do not allow the comingling of VA data with other, non-VA data, the NDSC has created a mirror database and website for the VA PRCs to collect the same data as the TBIMS National Database, and additional data items chosen by the VA PRCs. The VA will develop an SOP which will describe how VA PRC data can be accessed or analyzed for VA PRC and TBIMS collaborative study purposes.

The following is a description of the VA PRCs level of collaboration and what it involves.

Level I Collaboration – VA PRCs enrolling participants and collecting the same data as the TBIMS NDB, current module studies or new module studies.

Level IA – VA PRCs participating in the NDB (Form I and Form II) with or without participation in Collaborative Module Studies.

At the commencement of data collection, the VA PRCs should:
1) attend all Data Collector meetings and teleconferences;
2) attend the TBIMS Project Directors meetings as non-voting participants (who will be expected to pay registration fees);
3) subscribe to the data listserve and module listserves for modules for which they are collecting data;
4) participate if desired in Standing Committees (i.e, Data, Research, Dissemination and Planning) and their listserves, except as Chairs, and without voting privileges;
5) participate if desired in TBIMS Special Interest Groups (SIGs) listserves, teleconferences and meetings;
6) participate if desired in module study listserves, teleconferences and meetings for modules for which they are not collecting data;
7) be a co-investigator on projects analyzing TBIMS National Database data (which may involve access to analytic output or aggregate data); and
8) if desired, subscribe to the Notification listserve where new studies utilizing the TBIMS National Database data are posted and ask to join as an co-investigator on those studies.

Once it has been determined that the VA PRCs participation in the NDB and/or Module is of sufficient quality (meaning that the NDSC verifies the VA PRC is following the applicable items in SOP 107a - Data Quality Guidelines) after their first data submission and annually thereafter (each PRC will be responsible for meeting their data quality
targets and will receive feedback on those targets to ensure good data quality), they will continue with all activities listed above, and in addition should:

1) participate in the TBIMS Project Directors meetings as voting members who will be expected to pay registration fees and have 1 vote per center; except for Project Director votes for variable additions/deletions/piloting or changes to the inclusion/exclusion criteria for the TBIMS National Database;

2) subscribe to the TBIMS Project Directors listserve;

3) participate (except as Chairs) in Standing Committees (Data, Research, Dissemination, Planning), subscribe to those listserves, and have voting privileges on those Committees.

4) follow the TBIMS Internal Notification Policy (see Standard Operating Procedures Manual SOP#602b) to initiate projects analyzing TBIMS National Database data;

5) if desired, start and lead new SIGs.

Level IB – A VA PRC participating in a new module study: This would be a Collaborative Module Study that was not part of the TBIMS application and selection process. The development of a new collaborative module study must follow the procedure for the TBIMS internal module peer review; whether or not it includes VA PRCs (see Module Project Peer Review Procedures in the Standard Operating Procedures Manual SOP #700g).

In order for VA PRCs to participate in collaborative module studies, the NDSC would create a mirror database and website for their data so it does not comingle with the TBIMS data.

At the commencement of VA PRC module data collection, the VA PRC should:

1) attend all meetings/teleconferences pertaining to the module study;

2) subscribe to the module listserve;

3) and participate as a co-investigator in data mining studies only for the module study in which they are participating.

Once it has been determined that the VA PRCs participation in the module is of sufficient quality (defined above), they will continue with all activities listed above. They should follow the TBIMS Internal Notification Policy (see Standard Operating Procedures Manual SOP#602b) to initiate data mining studies only for the module study in which they are participating.

Level II Collaboration – VA PRCs that want the TBIMS to collect new data for their area of interest: This would involve a time-limited period of collecting specific data variables recommended by the VA PRCs with the intention of answering a specific research question. This type of collaboration is considered equivalent to development of a new collaborative module study and must follow the Module Project Peer Review Procedure in the Standard Operating Procedures Manual SOP #700g. This type of collaboration requires approval by the TBIMS Project Directors and agreement to participate by each participating TBIMS center.
Training requirements:
None

Compliance:
All TBIMS Centers, TBIMS Follow-up Centers, the NDSC and VA PRCs are responsible for adhering to this policy and its procedures.

References:
None

History:

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>5/27/2009</td>
<td>New Policy approved by Project Directors</td>
</tr>
<tr>
<td>9/13/2010</td>
<td>Revised draft specifically for VA PRCs</td>
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<tr>
<td>11/2/2010</td>
<td>Revised version approved</td>
</tr>
<tr>
<td>7/7/2014</td>
<td>Reviewed and minor clarifying changes made</td>
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<tr>
<td>6/12/2015</td>
<td>Updated NIDRR to NIDILRR</td>
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<tr>
<td>11/17/2016</td>
<td>Revised with changes to VA PRC privileges</td>
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Review schedule:
At least every 5 years