DA001 Identification of Subjects	
Review Committee: Planning	Start Date: 4/01/2007
Attachments: None	Last Revision Date: 12/19/2019
Forms: None	Last Reviewed Date: 12/19/2019

Introduction:

The TBIMS use established criteria to determine eligibility for enrollment and participation in the TBIMS National Database (NDB).

Purpose:

To institute standard inclusion / exclusion criteria for identifying and enrolling potential subjects into the NDB.

Scope:

Current TBIMS centers which are identifying and enrolling subjects into the NDB.

Responsibilities:

TBIMS staff responsible for identifying and enrolling subjects into the NDB (e.g., TBI researchers or clinicians, research assistants, study coordinators).

Procedural steps:

The Case Definition for inclusion in the NDB is:

TBI is defined as damage to brain tissue caused by an external mechanical force as evidenced by medically documented loss of consciousness or post traumatic amnesia (PTA) due to brain trauma or by objective neurological findings that can be reasonably attributed to TBI on physical examination or mental status examination. Penetrating wounds fitting definition listed above are included.

This definition of TBI excludes several conditions when criteria above are not met: Lacerations or contusions of the face, eye, or scalp, without other criteria listed above; Fractures of skull or facial bones, without criteria listed above; Primary anoxic, inflammatory, toxic, or metabolic encephalopathies which are not complications of head trauma; Brain infarction (ischemic stroke); Intracranial hemorrhage (hemorrhagic stroke) without associated trauma; Airway obstruction (e.g., near - drowning, throat swelling, choking, strangulation, or crush injuries to the chest); Seizure disorders (Grand mal, etc.); Intracranial surgery; Neoplasms.

Each potential TBIMS subject should be screened with the following inclusion/exclusion criteria.

The Inclusion Criteria for the TBIMS NDB are:

All persons:

1. fitting the above definition;
2. meeting at least one of the following criteria for moderate to severe TBI:
   - PTA > 24 hours
   - Trauma related intracranial neuroimaging abnormalities
   - Loss of consciousness exceeding 30 minutes (unless due to sedation or intoxication)
   - GCS in the emergency department of less than 13 (unless due to intubation, sedation, or intoxication);
3. who are age 16 or older at the time of injury;
4. presenting to the TBIMS's acute care hospital within 72 hours of injury;
5. must receive both acute hospital care and comprehensive rehabilitation in a designated brain injury inpatient rehabilitation program within the TBIMS. Comprehensive rehabilitation must occur in a hospital, rehabilitation unit, rehabilitation hospital, hospital-based skilled nursing facility, skilled nursing facility, or long-term acute care hospital that meets the following criteria:
   - Medical and rehabilitation care are supervised on a regular basis by a physician affiliated with the TBIMS
   - 24-hour nursing care is provided to the patient
   - PT, OT, Speech, Rehabilitation Psychology/Clinical Neuropsychology, and family support/education are provided in an integrated, team approach with the expectation of further gain.
   - Regardless the setting in which it is constituted, a comprehensive rehabilitation program operates in a manner consistent with (a) CARF standards for brain injury inpatient rehabilitation and/or (b) Medicare requirements for inpatient rehabilitation.
   - If a TBIMS's comprehensive rehabilitation program co-exists with programming that does not meet the above criteria, the TBIMS must explicitly define its methodology for establishing the dates of admission and discharge from comprehensive rehabilitation that will be reported to the TBIMS Data and Statistical Center (NDSC). These dates will represent the period of time during which CARF and/or Medicare criteria are met. This period may include interruptions during which the criteria are not met for medical reasons but after which a rehabilitation programming meeting CARF and/or Medicare criteria is resumed.
   - All data required by the National Database are accessible and transferable to the NDSC with appropriate informed consent;
6. who understand and provide informed consent to participate or, if unable, family or legally authorized representative understands and provides informed consent for the patient.

Additional Guidelines for inclusion/exclusion of cases are:

- Submit cases which expire any time after inpatient rehabilitation has begun; even if the patient was transferred back to acute care from rehabilitation prior to expiring.
- Subjects who have a preexisting central nervous system problem (anoxia, stroke, aneurysm, etc.) will be included in the database as long as all other inclusion criteria are met.
- Subjects who have concurrent events (e.g., aneurysm rupture with TBI, syncope/stroke/fall with TBI) will be included if the admitting physiatrist determines that the predominant mode of central nervous system injury is traumatic, as long as all other inclusion criteria are met.
- Subjects are included if the time of injury can be approximated within a 12-hour window. If time of injury cannot be approximately determined within 12 hours, the subject should be excluded.
- If date of injury is in question, it will be decided by the midpoint of the theoretical 12-hour (or less) window.
- If, prior to admission to comprehensive rehabilitation, a patient leaves a designated TBIMS facility for more than 72 hours, the patient should be excluded from the study. Once the patient enters comprehensive rehabilitation and meets the inclusion criteria, the subject should be retained even if she/he is subsequently transferred to a non-TBIMS facility.
- If a patient completes acute care and comprehensive rehabilitation and is then transferred outside of the TBIMS or to an alternate level of care that does not meet the criteria for comprehensive rehabilitation specified above (regardless of whether it is a designated TBIMS facility or not), this is considered the rehabilitation discharge date [RHB], and the residence at discharge [RES] should reflect this alternate level of care discharge.
- If a patient is transferred to an alternate level of care within the designated TBIMS prior to inpatient rehabilitation, the alternate level of care length of stay should be added to the TBIMS acute care stay [ACUTE] or comprehensive rehabilitation stay [RHB], whichever is most applicable.
- Do not exclude a person from the database because of early discharge from inpatient rehabilitation. There is no minimum amount of therapies that the patient must receive to be eligible.
- If patient expires prior to consenting, attempts should be made to obtain consent from family members in order to include data in the dataset (to avoid biasing the dataset).
- Patients who are in law enforcement custody at admission to the designated rehabilitation unit or who are taken into custody prior to discharge from the designated rehabilitation unit are not eligible for the TBIMS study and should not be approached for consent.

Training requirements:

Staff who are responsible for recruitment and enrollment of subjects into the TBIMS should be familiar with these criteria.

Compliance:

Only participants that meet these inclusion / exclusion criteria will be enrolled into the TBIMS NDB. These criteria should be reported in any presentations or publications related to analysis of the NDB data.

References:

Definition of TBI adopted from:

Thurman DJ, Sniezek JE, Johnson D, Greenspan A. Guidelines for Surveillance of Central Nervous System Injury, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control; 1995 (with some revisions from 2002).

History:

Date	Action
4/1/07	Version of inclusion criteria used to create this SOP
9/16/08	Transferred to SOP template and approved by SOP Review Committee
12/12/08	Revised definition with approval of Planning Committee and Project Directors
5/13/2012	Added language explaining that persons in law enforcement custody should not be enrolled in the TBIMS
1/1/2013	Updated variable numbers to variable group names
12/19/2019	Added language explaining that there is no minimum amount of therapies that the patient must receive to be eligible.

Review schedule:

At least every 5 years.

DA002 Sampling for NDB Enrollment	
Review Committee: Planning	Start Date: 10/1/2012
Attachments: None	Last Revised Date: 11/19/2019
Forms: None	Last Reviewed Date: 11/19/2019

Introduction:

The TBIMS uses established criteria to determine eligibility for enrollment and participation in the TBIMS National Database (NDB). To date, it has been the expectation that TBIMS centers approach every eligible subject for enrollment in the NDB. However, beginning on January 1, 2020 it is expected that through randomization of eligible cases a center will have a target of 35 cases per year. This SOP outlines the procedures that will take place for all centers, providing them with a sampling strategy that maintains the representativeness of their sample of subjects.

Purpose:

To institute standard procedural steps for enrolling subjects in the NDB and to address the issue of sampling for NDB enrollment.

Scope:

Current TBIMS centers enrolling subjects into the NDB.

Responsibilities:

TBIMS center staff responsible for enrolling subjects into the NDB (e.g., TBI researchers or clinicians, research assistants, study coordinators).

Procedural steps:

1. Centers are expected to enter into a screening database all TBI cases at or close to the time of admission.
2. Each subject will be screened for eligibility and if not eligible a reason for ineligibility will be marked (note: not all of the eligibility criteria need to be identified, just the first one noted in the record).
3. Once a subject is determined eligible, or if the case meets over-enrollment criteria (disorder of consciousness criteria) the researcher will click a randomization button which is linked to an algorithm that will choose whether or not that subject should be approached for consent based on the target number (35) and historical information such as number of eligible cases seen in a year and of those eligible, percent enrolled.
4. All sampling strategies and randomization procedures will be centralized at the NDSC and will be available for audit.

5. Subjects will be randomized after eligibility is determined but before being approached for consent.
6. The sampling methodology will be designed to enroll approximately 35 subjects per center in a 12-month period. The percentage of subjects randomly selected for consent will be based on a center's most recent year's statistics for eligible subjects and percent successfully enrolled.
7. It is expected that with small variations in performance, on any given year the actual number enrolled may fall short or exceed the target of 35. The NDSC will track quarterly the enrollment trends of centers and if the projections differ by +/- 5 subjects then a recalculation of the randomization cut point may be considered.

Algorithm:

$$Randomization\ cut\ point = \frac{\boldsymbol{Target\ Number}}{Eligible\ last\ year * Percent\ enrolled\ last\ year}$$

Example:
If a center has 58 eligible persons in the past year and successful consented 85% of them, their randomization cut point will be 71.

Randomization generator:
The database will generate a random number between 1 and 100 using the formula `@Result = 1 + ABS(CHECKSUM(NEWID())) % 100;` Comparing this number to the randomization cut point will decide whether an eligible subject should be approached. If the randomization number is equal to or less than the randomization cut point, then the researcher will be directed to approach patient for consent, conversely, if the number is greater that the cut point the they will be directed to not approach the patient for inclusion into the study.

Training requirements:

None

Compliance:

All TBIMS centers who are enrolling subjects into the NDB and the NDSC will comply with this procedure.

References:

None

History:

Date	Action
6/17/2011	SOP Created and Approved by Project Directors
10/1/2012	Start date of SOP

Date	Action
6/12/2015	Updated NIDRR to NIDILRR
1/27/2016	Added example calculations
10/1/2019	The SOP changed from randomizing only centers who had large enrollments (over 70) to randomizing all centers to target 35 enrollments per year
10/1/2019	Removed NIDILRR from Compliance section

Review schedule:

At least every 5 years.

DA003 Guidelines and Strategies for TBIMS National Database Recruitment & Consenting

Review Committee: Data	Start Date: 4/01/2007
Attachments: None	Last Revised Date: 3/20/2023
Forms: None	Last Reviewed Date: 3/20/2023

Introduction:

The TBIMS use established procedural steps to recruit and consent potential participants in the TBIMS National Database (NDB) including strategies and considerations for recruitment and consent.

Purpose:

To institute standard procedural steps for recruiting and consenting potential subjects into the NDB.

Scope:

Current TBIMS centers which are recruiting and consenting participants into the NDB.

Responsibilities:

TBIMS staff responsible for recruiting and consenting into the NDB (e.g., TBI researchers or clinicians, research assistants, study coordinators).

Procedural steps:

Who should be approached for consent?

- All individuals who meet the inclusion criteria and are identified through the NDB sampling procedures (SOP 103) – potential subjects are eligible regardless of immigration status, residence, language barriers, anticipated or actual length of stay, ease of follow up etc. as established by the center's IRB requirements.
- Centers should use local institutional resources and policies for providing translation for the consent process when the patient and/ or consenting family member does not speak English.
- Persons with TBI &/or their SO (if the individual with TBI does not have capacity for consent)
- Centers should be aware of their individual IRB procedures for determining the capability to give informed consent.

Who can approach potential participants?

- A member of the clinical team
- A member of the research team
  - HIPAA consideration: At some institutions, interpretations of HIPAA regulations may require that permission for research staff contact be given by the potential participant/SO to a member of the clinical team.
  - Members of the research team may have a better understanding of the parameters of data collection and the research projects.
- A potential participant may initiate contact with the research team.

When should potential participants first be approached and subsequent informed consent pursued?

- Acute care hospital (if it is known that the person will be transferred to the TBIMS inpatient rehabilitation facility) or acute rehabilitation hospital.

When do you stop approaching for consent?

- Continue to re-approach until nine months post-discharge from TBIMS inpatient rehabilitation facility, until consent is obtained or until the investigators and research staff make a judgement that the participant or their proxy does not wish to participate.

What if consent/participation is refused?

- Record as refused consent and do not re-approach.

Is formal annual re-consent needed?

- No, unless your IRB requires it. Consent is an ongoing process. At the beginning of each annual follow-up contact it is generally a good idea to briefly review the project, the reason for the call and what will be asked, and to confirm permission to proceed with the contact.
  - A participant may refuse further participation or decide to withdraw from the study at any time. If so,
    - Clarify their intent: withdrawal or selective non-participation.
    - If withdrawn, the participant would be recorded as withdrawn from further model system follow up data collection and no further data collection or contact would occur.
    - A participant may choose not to answer a specific question, set of questions, or participate for a specific follow up interval, but still be allowed to participate in other data collection and subsequent years. In this situation the participant would still be considered a model system participant and not withdrawn.

Documentation and storage of signed consent forms or forms completed when a waiver of documentation of consent is approved by your IRB:

- Copy of consent form or documentation of verbal consent to research files (electronic or physical)
  - Your local IRB/ privacy office may be a helpful resource to learn about storing consent forms in a manner that maintains privacy.
- Copy of consent form or documentation of verbal consent to participant/SO

- Copy on chart
  - Caution: Clarify with your IRB as each local project and IRB may have unique considerations and requirements, especially regarding chart copies of study consent forms or documentation of verbal consent.

Inclusion of consent for Geographic Identifiers (GEO-ID):

- Ideally, the consent will include permission to share the participant's address with the NDSC.
- Participants should be able to "agree" or "not agree" by providing their initials to a statement as approved by their IRB. The following is an example:
  - The TBI Model System research team has my permission to provide my address to the National Data and Statistical Center (NDSC). This does NOT give the NDSC permission to contact me. My address will only be used to get information about the community where I live. Studies show that the places where people live are important to their health and wellbeing.

Inclusion of consent for Federal Interagency TBI Informatics System (FITBIR):

- The consent should include permission to share the participant's data with FITBIR.
- Participants should be able to give their permission (or not) as approved by their IRB. The following is an example of verbiage that could be used:
  - To maximize the value of the data we collect about recovery from TBI, the TBI Model System would like to combine our data with data collected in other studies on TBI. We need your permission to do this. With your permission, the data we collect about you, without personal identifiers, will be added to the Federal Interagency TBI Informatics System, known as FITBIR. The FITBIR database was established by the United States Department of Defense (DoD) and the National Institutes of Health (NIH) and serves as the data repository for many TBI research studies. There will be no cost to you or any additional responsibilities for you to participate in this project. The data collected as part of the TBI Model System will be de-identified and transmitted securely to the FITBIR database coded with a global unique identifier (GUID) which will allow researchers to share data without exposing personally identifiable information.

Coercion

Any research involving human subjects is guided by regulations provided in CFR Title 21 regarding the proper consent process. For example, Data Coordinators, Clinicians and Investigators should be cautious when approaching subjects and their families and not be coercive when discussing their participation in the TBIMS. We recommend referencing resource materials that will help navigate these regulations, such as, http://www.clinicalresearchresources.com/books/bookstore.html and http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm

What is coercion?

- Coercion is the practice of compelling a person to behave in a certain way (whether through action or inaction) by use of threats, intimidation or some other form of pressure or force.
  - Clinicians should be aware that in the clinician–patient relationship that the clinician may hold a potential "power" or perception of power over the patient.
  - Although overt coercion is easy to spot (and to avoid), clinicians should also be aware of more subtle influences on the patient approached for research by a trusted member of his/ her clinical team. For example, a patient may think "This has to be okay because my doctor wants me to do it" and thus fail to think carefully through the risks and benefits.
  - Patients commonly believe that they will benefit personally from research or that the research project is part of clinical care, even when told otherwise. Being offered participation in a research project by a clinical team member may further blur the boundaries and exacerbate confusion about the nature of the research.
- Tips to avoid coercion or unintended pressure:
  - Have the clinician ask the patient if he/she can be approached by a research staff person in order to discuss potential research projects, and have the research staff person explain and obtain written consent.
  - Don't put too much focus on monetary incentives.
  - Don't promise any direct benefit.
- These points should not be interpreted to mean that clinicians should not be involved in recruitment. On the contrary, clinicians are often in the best position to answer questions the potential participant may have about the study. Referring the patient to a clinician for the purpose of explaining the research is not considered coercive (as long as the patient has not already declined participation).

Strategies for a Successful Research Recruitment Campaign

- Understand your subject population pool. (This may be especially important for minority populations – i.e., that there are over 500 Native American tribes and over 100 dialects spoken among Asian American Pacific Islanders). Review materials related to cultural humility on the NDSC website (https://www.tbindsc.org/Members/Cultural.aspx).
- Establish rapport and trust in the program and staff.
- Ensure that all recruitment staff is properly trained and that their skills are assessed regularly.
- Promote awareness of the project.
- Promote interaction with direct-care staff.
- Secure translators for commonly seen ethnic groups.
- Explain real benefits of participation in clinical research (contribution to science, advance new learning). Note: Don't overplay the expected project benefits.
- Enhance the capability and perceived self-efficacy of potential participants to participate (this has proven very effective in the minority populations).
- Understand the needs, fears, and attitudes of participants about research and their condition.
- Help participants solve problems interfering with participation.

- As opportunities present themselves, help participants meet needs not directly related to your research project (e.g., identifying needed resources, such as specialty physician care or agencies that can help with applications for state or federal aid).
- Take an educational approach to project involvement and recruitment.
- Distribute an educational packet or brochure that includes information about TBI in general and information about your specific project.
- Obtain business cards for research and clinical staff.
- Post photos of research team members on the unit.
- Arrange for permissions to add research appointments to patients' schedules.
- Have direct-care staff share research brochures with patients.
- Leave MSKTC flyers in patient's room.

Strategies for approaching for consent post-discharge:

- Attempt to consent should begin shortly after discharge (allow a few days for patients to get settled before calling).
- Check with members of the clinical team regarding their impressions on capacity to consent at discharge and plan how to approach accordingly (person with TBI vs SO).
- If you have not been able to reach an eligible participant after 2 weeks of attempted contact, try to:
    - Complete phone call attempts at each of the following times: normal business hours (at different times of day); weekday evenings (on different days of the week); and weekends.
    - Check with providers to see if the patient may be returning for an outpatient clinic appointment. Make arrangements to be in clinic at their appointment time. Ask to be introduced to the patient after the visit, so that you can share information about the research program.
    - Send an introductory letter and copy of the consent form to the eligible participant or a family member that was involved with their care while in rehabilitation.

Considerations in approaching elderly patients/caregivers for consent:

- Address the person as "Dr." or "Mr." or "Mrs." or "Ms." unless they tell you to call them by their first name.
- Ask patient's permission to include caregiver in discussion.
- Continue to include patient in conversation (eye contact, etc.) even if the caregiver is acting as proxy.
- Be sure that all parties can hear you and see you.
- Speak slowly, allowing time for information to be processed.
- After explaining study, offer to leave the consent with them to review, letting them know that you will return at an established time to follow up.

Training requirements:

Whatever your TBIMS center or IRB requires (e.g., HIPAA training, IRB training, Cultural Competency/Diversity training).

Compliance:

Comply with institutional/IRB policies and procedures. Each Model System will review specific procedures and policies regarding recruitment and consent with the NDSC during the quality support visits.

References:

Berlin EA, Fowkes WC, Jr. A teaching framework for cross-cultural health care. Application in family practice. *West J Med* 1983; 139(6):934-938.

History:

Date	Action
04/01/2007	Version of inclusion criteria used to create this SOP
09/16/2008	Transferred to SOP template and approved by SOP Review Committee
10/01/2008	Added stop time for attempting consent as 3 months post-discharge
12/12/2008	Revised definition with approval of Planning Committee and Project Directors
06/19/2011	Changed the time to consent from 3 months post discharge to nine
01/01/2013	Removed bullet regarding collection of reason for refused consent
09/08/2014	Removed note on coercion within the section," Who can approach potential participants." Added links for additional guidance on avoiding coercion: http://www.clinicalresearchresources.com/books/bookstore.html and http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm . Added section on approaching elderly patients/caregivers for consent.
02/19/2018	Added "Leave MSKTC flyers in patient's room." to list of strategies.
10/01/2019	Removed Cultural Considerations
08/27/2020	Added note about sampling for NDB enrollment
03/10/2023	Added "Post photos of research team members on the unit, Arrange for permissions to add research appointments, and Have direct-care staff share research brochures" to list of strategies
03/10/2023	Added "Strategies for approaching for consent post-discharge" section
03/10/2023	Added instruction regarding storage of documentation of consent when completed verbally.
03/10/2023	Added details regarding storage of documentation of verbal consent.
03/10/2023	Added instructions regarding consent for GEO-ID and FITBIR.

Review schedule:

At least every 5 years.

DA004 Guidelines for Medical Record Abstraction and Record Requests

Review Committee: Data	Effective Date: 10/01/2019
Attachments: FAX Cover Sheet Examples	Revised Date: 06/24/2019
Forms: None	Reviewed Date: 06/24/2019

Introduction:

Form 1 data collection includes abstraction of certain variables from the participant's medical record. In order to access these records from outside facilities, data collectors need to request them from these facilities after obtaining a signed release of information from the participant or legally authorized representative.

Purpose:

To provide general guidelines for the collection of medical records in order to code TBI Model Systems variables. Each Model Systems center should ensure that their site procedures for collecting this data are approved by their local IRB.

Scope:

Current TBIMS centers which are identifying and enrolling subjects into the NDB.

Responsibilities:

TBIMS staff responsible for Form 1 medical record request and abstraction of Form 1 data.

Procedural steps:

1. **Identification of Facilities to Request Records From**
    a. There is no rigid rule regarding when to begin the medical record request (and coding) process. Sites may choose to begin the process upon consenting the participant. At minimum, the process should begin within 1-2 weeks of the start of a new quarter (1/01, 4/01, 7/01, 10/01) to ensure adequate time for receiving and reviewing the records, coding the variables, and entering the data on the NDSC website prior the data upload deadline (3/31, 6/30, 9/30, and 1/15).
    b. Prior to requesting records from the acute stay, it may be advantageous to first abstract all items available from the rehabilitation record. If there are gaps, additional records can be requested as needed.
    c. Identify which acute facilities participant was treated at following the TBI prior to rehab admission (this can typically be found in the History and Physical, transfer notes or copies of outside records, including but not limited to:

- Emergency department visits
- Acute hospitalization (civilian or military)
- Long-term acute care (LTAC) hospitalization

d. If the participant was transferred to a non-TBIMS facility prior to rehab admission, they would be considered to NOT be continuously hospitalized and therefore not eligible. Discontinue data collection and do not include this person in your TBIMS.

2. Request and Collect Medical Records

a. Contact each facility's medical records department to determine their process for requesting records. Most centers will require a copy of the consent form for each participant and/or a signed release of information form (ROI). The facility may choose to send the record by one a variety of methods including but not limited to:
   - Mailing a CD or paper copy of the record
   - Emailing a PDF of the record
   - Authorizing access to view the record at the facility
   - Authorizing remote access to view the record online.

b. If the facility will be sending copies of the record, the specific records needed to complete Form 1 abstraction should be included in this request (ED Records, EMS Transport records, ICD-10 Final Diagnosis Codes, Trauma Intake, History and Physical, Head CT, Neurosurgery Consult, Discharge Summary, Neuro Checks, Flowsheets and Progress Notes).
   - For persons who are following commands at rehab admission, but are not yet oriented, progress notes from the acute facilities are necessary to determine date the participant was able to follow commands.
   - For persons who did not regain command following until rehab admission, progress notes from the acute care setting are still necessary to confirm that the participant had not regained but then lost command following ability while in acute care.

c. Send record request with the required paperwork (consent and/or ROI) to each facility. (See attached FAX cover sheet examples.)
   - Acute hospital (initial)
   - Acute hospital (progress notes only)
   - LTAC (initial)
   - LTAC (progress notes only)
   - SNF, or other non-hospital care

d. If no records received within 2 weeks, follow-up with facility.

3. Problem Solving

This section details some common problems encountered when attempting to obtain outside medical records, and suggested strategies:

Problem	Suggested Solution(s)
Medical record just says person was transferred from an OSH (outside hospital).	• Look elsewhere in the medical record. • Ask the participant (or health care proxy) for the name and location of the prior hospital. • Ask the physiatrist, social worker, nurse manager, or neuropsychologist on the unit where the participant was hospitalized.
The named hospital has multiple locations (e.g., St. Joe's North, St. Joe's South). Not sure which one the participant was hospitalized.	• Ask the participant (or health care proxy) for the location of the prior hospital (the street name or what part of town it was located). • Ask the physiatrist, social worker, nurse manager, or neuropsychologist on the unit which hospital the participant was hospitalized prior to rehabilitation admission.
The participant was hospitalized at multiple locations prior to Rehab admission. What should I do?	• Look in the medical record for the names of each hospital prior to rehab admission. • Ask the participant (or health care proxy) for the name and location of each prior hospital. • Ask the physiatrist, social worker, nurse manager, or neuropsychologist on the unit where the participant was hospitalized, for each prior hospitalization. • If you have an H&P and/or Discharge Summary from one or more of the prior hospitals, often they name the hospital to/from which the patient was transferred.
Some but not all records I requested were sent.	• Review received records and code the medical record abstraction form to the degree possible. If there are variables un-coded due to lack of information (usually TFC and PTA because no (or limited) progress notes were sent), re-request records that will likely contain the missing items (e.g. progress notes). Follow up with a phone call to be sure the fax was received.
Facility indicated that no patient by that name was seen at that hospital.	• Check to verify that the spelling of the patient's name and date of birth on the ROI are correct. Also check to ensure the time frame of hospitalization is correct. If the patient is known by a different name (e.g., patient's name changed due to marriage), be sure both the maiden name and the married name are listed on the ROI. If the hospital system that the ROI was sent is a system with multiple hospital locations, verify that the ROI was sent to the hospital at which the patient was treated.
The medical records staff member at the acute facility told me that there are too many records to fax.	• Ask if they can fax the H&P, Discharge Summary, ED Reports and CTs, and mail the rest of the records, or mail a CD with the records.

4. **Storage of Outside Records**
    a. Each TBIMS center should ensure that their site procedures for storing research records are approved by their local IRB.
    b. Options for storage may include the following:
        - Hard copies in a research chart with the TBIMS ID#
        - Records scanned into a secure drive on the center's local network
        - Records scanned to a CD or secure media and stored in the research chart with the TBIMS ID#

Training requirements:

None

Compliance:

All

References:

None

History:

Date	Action
10/01/2018	Draft created by VA PRC TBIMS centers
10/01/2019	Approved by SOP Review Committee for TBIMS use

Review schedule:

At least every 5 years.

FAX

FROM:

Date:
To: [name of acute hospital] FAX#:
From: Dr. X [PI's Name]
Attention: Release of Medical Records
RE: Patient's Medical Records
No. of pages *including* cover: 2

Medical Records Request

Patient's Name: **DoB:** **Date(s) of Interest:** [date of injury to date of discharge from acute hospital]	**Record including:** • Emergency Dept Intake (ER Records) • Trauma Intake • History and Physical • Discharge Summary • Neurology Consult • Neurosurgery Consult • Psychology Consult • Psychiatry Consult • Neuropsychology Consult • Social Work Consult Note • Head CT Radiology Reports ***Do NOT need labs/chemistry.** ***Head/Brain CT reports only. Do NOT need radiology reports for cervical spine or other body areas.**

Please **fax** records to
Attention:

Contact:

FAX

FROM:

Date:
To: [name of acute hospital] FAX#:
From: Dr. X [PI's Name]
Attention: Release of Medical Records
RE: Patient's Medical Records
No. of pages *including* cover: 2

Medical Records Request

Patient's Name: **DoB:** **Date(s) of Interest:** [date of injury to date of discharge from acute hospital	**Record including:** • Physician's Progress Notes • Attending's Progress Notes • Trauma Progress Notes [Also include the following if they also received rehabilitation services during the acute care hospitalization] • Speech Language Therapy Consult/Evaluation • Speech Language Therapy Progress Notes • Occupational Therapy Consult/Evaluation • Occupational Therapy Progress Notes • Physical Therapy Consult/Evaluation • Physical Therapy Progress Notes

Please **fax** records to
Attention:

Contact:

FAX

FROM:

Date:
To: [name of LTAC] FAX#:
From: Dr. X [PI's Name]
Attention: Release of Medical Records
RE: Patient's Medical Records
No. of pages *including* cover: 2

Medical Records Request

Patient's Name: **DoB:** **Date(s) of Interest:** [date of admission to LTAC to date of discharge from LTAC]	**Record including:** • History and Physical • Discharge Summary • Neurology Consult • Neurosurgery Consult • Psychology Consult • Psychiatry Consult • Neuropsychology Consult ***Do NOT need labs/chemistry.**

Please **fax** records to
Attention:

Contact:

FAX

FROM:

Date:
To: [name of LTAC] FAX#:
From: Dr. X [PI's Name]
Attention: Release of Medical Records
RE: Patient's Medical Records
No. of pages *including* cover: 2

Medical Records Request

Patient's Name: **DoB:** **Date(s) of Interest:** [date of admission to LTAC to date of discharge from LTAC]	**Record including:** • Physician's Progress Notes • Attending's Progress Notes [Also include the following if they also received rehabilitation services during the acute care hospitalization] • Speech Language Therapy Consult/Evaluation • Speech Language Therapy Progress Notes • Occupational Therapy Consult/Evaluation • Occupational Therapy Progress Notes • Physical Therapy Consult/Evaluation • Physical Therapy Progress Notes

Please **fax** records to
Attention:

Contact:

FAX

FROM:

Date:
To: [name of SNF or other non-hospital] FAX#:
From: Dr. X [PI's Name]
Attention: Release of Medical Records
RE: Patient's Medical Records
No. of pages *including* cover: 2

Medical Records Request

Patient's Name: **DoB:** **Date(s) of Interest:** [date of admission to date of discharge]	**Record including:** • Intake / Admission • History and Physical • Discharge Summary • Progress Notes [include this if you suspect the person may have begun following commands or emerged from PTA]

Please **fax** records to
Attention:

Contact:

DA005 Instructions for Administration of the Pre-Injury History Interview/Questionnaire

Review Committee: Data	Start Date: 2/17/2004
Attachments: None	Last Revised Date: 1/1/2013
Forms: DAF102 – Form 1 Pre-Injury History Interview; DAF103 – Form 1 Pre-Injury History Questionnaire	Last Reviewed Date: 2/11/2020

Introduction:

The Form 1 data collection of the TBIMS National Database requires the use of the Pre-Injury History Interview/Questionnaire to be collected from the patient and/or family as soon as it is possible after the participant has been enrolled into the TBIMS.

Purpose:

To institute a standardized method for collecting pre-injury history items on the TBIMS Form 1.

Scope:

All current TBIMS centers collecting Form 1 data.

Responsibilities:

All current TBIMS staff who collect pre-injury history information.

Procedural steps:

The Pre-Injury History Interview or Questionnaire should be used to collect relevant data for the TBIMS National Database Form 1. Exact wording of questions is provided. The Pre-Injury History Interview and Questionnaire forms are available on the NDSC website. Centers should not be using their own data collection methods or forms.

The pre-injury history information is to be collected as soon as possible after injury, whether from the person with TBI or from a family member/significant other. The objective is to get accurate information, from the most reliable source. If information cannot be obtained during inpatient rehabilitation, continue to attempt to collect this information up until the Form 2 year 1 data collection window closes, taking care to distinguish the difference between pre-injury occurrences and occurrences during the follow-up period.

Form 1 demographic questions are included in the questionnaire because, with the exception of date of birth, it is preferable to collect this information from the patient or a well-informed significant other rather than from medical records. Asking these easy-to-answer demographic questions also helps to establish rapport with the respondent prior to the more sensitive questions.

The Pre-Injury History Interview can be used for in-person interviews or phone interviews. The Pre-Injury History Questionnaire can be used as a self-administered questionnaire, or it can be mailed to the person with brain injury and/or family member. The Pre-Injury History Interview or Questionnaire should be given to the person who, based on the clinician/data collector's opinion, can supply the most accurate information.

Family members or patients may be unsure of their answers to some questions (e.g., drug and alcohol use/abuse). Do not encourage individuals to guess at answers; but do encourage them to answer all questions. When coding data later, enter the appropriate code to indicate that the question was asked but not answered (e.g. "unknown"). [We deliberately chose not to list a "don't know" or "unknown" response alternative on the questionnaire. Past experience indicates that such alternatives substantially increase the rate of unusable responses.]

For prospective data collection, information collected using this questionnaire should be entered into the database as part of the Form 1. For retrospective data collection, information collected using this questionnaire should be updated on the Form 1 already entered into the database.

Training requirements:

The Pre-Injury History Interview/Questionnaire is discussed at the Data Collectors conferences as well as a possible topic for the quarterly Data Collectors teleconferences.

Compliance:

All collaborating centers utilizing the TBIMS National Database are responsible for adhering to this policy and its procedures. The NDSC will determine if the questionnaire is used as part of the Quality Support Visits.

References:

None.

History:

Date	Action
2/17/2004	Version of inclusion criteria used to create this SOP
9/16/2008	Transferred to SOP template and approved by SOP Review Committee
12/12/2008	Revised definition with approval of Planning Committee and Project Directors
1/1/2013	Updated Pre-morbid to Pre-Injury; Updated language to include Pre-Injury Interview and Questionnaire
09/08/2014	SOP Reviewed
2/11/2020	SOP Reviewed

Review schedule:

At least every 5 years.

DA006 Guidelines for Collection of Follow-Up Data

Review Committee: Data	Start Date: 4/01/2008
Attachments: None	Last Revised Date: 09/12/2022
Forms: None	Last Reviewed Date: 8/27/2020

Introduction:

The TBIMS uses an established set of rules including procedural steps for follow-up data collection (FORM 2) for the TBIMS National Database (NDB).

Purpose:

To institute a standard procedure for collection of follow-up data for the NDB.

Scope:

TBIMS and TBIMS longitudinal follow-up centers that collect follow-up data for the TBIMS NDB.

Responsibilities:

TBIMS staff responsible for Form 2 data collection for the TBIMS NDB (e.g., TBI researchers or clinicians, research assistants, study coordinators).

Procedural steps:

- For the first year of follow-up, data collection should occur within 2 months before to 2 months after the anniversary date of the injury. For follow-up year 2, data collection should occur within 3 months before to 3 months after the anniversary date of the injury. For follow-up years 5 and thereafter, data collection should occur within 6 months before to 6 months after the anniversary date of the injury.
- Centers should run the Inter-Form Values by Subject ID report prior to completing a Form 2 for a participant.
- If possible, the participant should be asked to stay on the phone after collection of Form 2 data, so that the error checks can be run and any questions clarified.
- If a participant expires during initial inpatient rehabilitation, no Form 2 is to be completed. If, however, the participant expires after rehabilitation discharge but before the next Form 2 window, the Form 2 should be completed and coded as expired.
- If a participant is still in their first inpatient rehabilitation stay at the time that their first anniversary of injury follow-up window is about to close, collect the Form 2 Year 1 follow-up information within the follow-up window. The rehabilitation hospital would be the residence, living with other patients; FIM/DRS should be obtained at that time.

- Follow-up should be attempted according to the TBIMS schedule for every participant (person with TBI) for whom a Form 1 was submitted, unless the participant was reported as expired or withdrew authorization to collect data in a prior follow-up year.
- If a participant withdraws authorization, that means that they do not wish to participate in any data collection from the time of withdrawal forward and will not be contacted again. It does not mean that all of their previously collected data is deleted from the database. Participants wishing to withdraw from the study should not be asked if they want all their previous data deleted from the database; however, if they state they want all their previous data deleted then it should be deleted.
- A participant may refuse to be interviewed because they are too busy or do not wish to be bothered, etc. This would be considered a refusal and not a withdrawal. If this is the case, the interviewer should ask if he/she can contact the participant again. The interviewer should also gently suggest rescheduling the interview to a later time in the Form 2 window, or offer the mail-out version of Form 2.
- If a proxy refuses for the participant and the participant has full capacity for decision making, the proxy should be informed that the refusal needs to come from the participant. If confirmation of refusal from the participant cannot be obtained, it is recommended to code as lost. If a proxy wants to withdraw the participant (or states that the participant wants to withdraw) and the participant has full capacity for decision making, the proxy should be informed that the withdrawal request needs to come from the participant. If this cannot be confirmed, either by phone or in writing, do not withdraw the participant, code current follow-up as lost, and attempt to contact at next follow-up.
- The primary source of information for the annual follow-up should be the participant. If the participant does not or cannot respond to certain questions or to all questions, then the significant other who knows the participant best becomes the participant's proxy and may answer for the participant.
- A "significant other" is someone who knows the participant well and is available, able, and willing to answer questions reliably about that individual's daily life. This person is typically a family member but is not required to be related to the participant or to live with that person. A significant other may be a non-traditional person such as a nurse at the facility where the person resides, a legal/public guardian, a roommate, a close friend, etc. The significant other must know the participant sufficiently well to answer questions accurately. The significant other may qualify to answer some questions but not others.
- Questions that the proxy cannot answer reliably are coded as "unknown". The proxy must not answer [SWLS], [GNHLTH], [BTACT], [PHQ9], and [GAD7].

When a person *cannot be interviewed[1], has expired, withdrawn authorization, refused to be interviewed, or is incarcerated, a limited amount of information – shown in the table below – is to be entered onto the Form 2.

[1] As specified in the Guidelines and Strategies for Maximizing Follow-up SOP.

GROUP /VARIABLE	LOST	EXPIRED	WITHDREW	INCARCERATED	REFUSED
	Attempt follow-up at next follow-up window opening.	No further follow-up.	No further follow-up.	Attempt follow-up at next follow-up window opening to determine if still incarcerated.	Attempt follow-up at next follow-up window opening.
KEYS	Center ID Subject ID Follow-up year	Center ID Subject ID Follow-up year	Center ID Subject ID Follow-up year	Center ID Subject ID Follow-up year	Center ID Subject ID Follow-up year
If lost, why?	Code reason lost	82-NA, Expired	81-NA	81-NA	81-NA
FU/FollowUp	07/07/7777	04/04/4444	05/05/5555	07/07/7777	07/07/7777
CSEDTH/ DeathF	09/09/9999 (08/08/8888 if known to be alive)	[expiration date]	08/08/8888	08/08/8888	08/08/8888
CSEDTH/ DeathCause1F DeathCause2F	99999 (88888 if known to be alive)	[ICD-9 Codes] To be completed by the NDSC	88888	88888	88888
CSEDTH/ DeathECodeF	99999 (88888 if known to be alive)	[External ICDCode] To be completed by the NDSC	88888	88888	88888
RES/ResF	blank	blank	blank	04	blank
all other variables	blank	blank	blank	blank	blank

- EXPIRED or WITHDREW AUTHORIZATION. For participants who have expired or who withdrew authorization to continue with the study, enter the information shown in the table above. If the data collector learns prior to window opening that the person expired or withdraws authorization, the above information may be entered at any time up to and including the quarter in which the follow-up would have been due. Regardless of the quarter in which this information is entered, the "Follow-Up Period" is coded as the year of the follow-up that would have been due (e.g., year 01, year 02, year 05, et cetera). For expired participants and those who withdraw authorization, no additional Form 2's are ever entered.
- INCARCERATED. Data should not be collected from the participant or from a proxy while the participant is incarcerated. Find out if the incarcerated person will be released

prior to the closing of the data collection window (only if obtaining such information is acceptable to your IRB and Investigator). If the person will be released before the window closes, then complete Form 2 data should be collected between the time of release and window closing. Do not collect follow-up information about participants who are incarcerated throughout the follow-up window. For these participants--and for participants who were released prior to window closing but about whom data was not able to be collected--enter the data shown in the table above. If unable to reach a participant to complete a follow-up, and the participant was incarcerated for half or more of the follow-up window, the participant can be coded as incarcerated. Persons who are on house arrest should be treated as incarcerated, however a person on parole or probation can be followed, as long as they are free to come and go as they please. If there is any question about the definition of prisoner, centers should check with their individual IRB and review OHRP guidelines (US Dept of Health & Human Services Office for Human Research Protections.)

- Follow-up evaluations that have been started or completed prior to the window start date should have a call back during the window to clarify that nothing has changed. The date of the call back occurring within the follow-up window should be used as the interview date. If a call back cannot be completed, the original interview date outside the follow-up window should be used.
- To classify an interview as "followed" an interview or mail-out must be started. There is no minimum number of data elements that need to be answered, but you must have more than the participant's living status.
- Follow-up evaluations that have been started but cannot be completed by the time the data collection window closes can be completed within two weeks after the window closes. The interview date should be the date the interview was started.
- Follow-up evaluations that have been started but not completed during the first contact should be completed within 4 weeks. The follow-up date should be the date of initial data collection. If it takes longer than 4 weeks to complete the follow-up, data collected during the initial data collection period should be verified, and the follow-up date should be the second date that data was collected. Mail-outs will be exempt from the 4-week rule. In the unusual case where the 2-week extension window is used to complete the follow-up beyond the 4-week time frame, (e.g., interview started January 1st, follow-up window closes January 30th, interview completed February 5th), the follow-up date should be the date of data collection that was in the follow-up window (January 1st in this example).
- Missing data may not be filled in using data obtained outside the follow-up window. Data collected outside the follow-up window may not be added to Form 2's that were originally entered without data. Data may be obtained outside the follow-up window from sources that had collected the data within the follow-up window--for example, data collected by clinicians during a clinical follow-up which occurred during the follow-up window.
- If phone contact with the participant is not possible, all information except: [SWLS], [GNHLTH], [BTACT], [PHQ9], and [GAD7] should be collected from a significant other by phone. The participant should be sent the [SWLS], [GNHLTH], [BTACT], [PHQ9], and [GAD7] items by mail, along with a self-addressed return envelope if these

questionnaires can be completed.

- If telephone contact with the participant and significant others is not successful, the participant should be sent the mail-out version of the Form 2 after personalized information (name, enrollment date, name and contact information of Form 2 data collector) has been added to the form, along with a self-addressed return envelope.
- If adequate data are not obtained from the participant by telephone or by mail-out, the mail-out Form 2 should be sent to the significant other after personalized information (name, enrollment date, name and contact information of Form 2 data collector) has been added to the form, along with a self-addressed return envelope.
- Centers are not required to keep a paper printout of Form 2 but are strongly encouraged to back up their quarterly data in some form: paper, excel download, PDF.

Training requirements:

Staff persons who are responsible for the Form 2 data collection for TBIMS should be familiar with these criteria. On-going training will be conducted by quarterly data collector teleconferences and in-person data collectors' meetings.

Compliance:

All follow-up data collectors are required to comply with these guidelines, and attend the quarterly data collector teleconferences and in-person data collectors' meetings.

References:

None

History:

Date	Action
4/1/2008	Version used to create this SOP.
9/16/2008	Transferred to SOP template and approved by SOP Review Committee.
12/12/2008	Revised to clarify difference between refused and withdrawn, and added PHQ-9 as variable not collected from proxy. Approved by Data Committee, SOP Committee, Planning Committee and Project Directors.
	Added clarification about not interviewing persons that are on house arrest. A person on parole or probation should be followed.
	Added rule about interviewing subject prior to the window open date.
10/1/2010	Added GAD-7 to list of items that cannot be completed by a proxy.
11/17/2011	Clarified the Interview date to be entered if partial information was achieved outside of the follow-up window.
1/1/2013	Updated variable #'s to new variable group names. Table updated to new order. Added new variable group GNHLTH to list of items that cannot be completed by a proxy.

4/1/2013	Added bullet regarding centers not being required to keep printout of Form 2.
10/1/2013	Updated SOP to reference newly added QOL variable, and to expand on contacting prisoners.
9/8/2014	Removed the referenced form, as it is now part of online data entry (Guidelines and Strategies for Maximizing Follow-Up form). Within Procedural Steps: (1) bullet added that centers should run the "Inter-Form Values by Subject ID" report prior to completing a Form 2; (2) bullet added that the participant should remain on the phone (if possible) while error checks are run, so that any questions can be clarified; and (3) bullet added regarding classifying a case as "followed."
12/01/2015	Added clarifications regarding proxy refusals.
12/01/2015	Added a follow-up window of 4 weeks for cases started but not completed on first contact.
1/15/2017	Deleted completion instructions for INTMTHD variable group. (This variable group was deleted from the Form 2 data collection form.)
9/30/2018	Added note to "Incarcerated" bullet – "If unable to reach a participant to complete a follow-up, and the participant was incarcerated for half or more of the follow-up window, the participant can be coded as incarcerated."
8/27/2020	BTACT, PHQ9, GAD7 added to list of items not to be collected from an SO. QOL removed from list. Further explanation added regarding when a participant expires between rehabilitation discharge and Form 2 data collection. Further guidance added regarding handling refusals (versus withdrawals).
7/6/2021	Changed "refusal" to "lost" in bullet regarding how to code when a proxy refuses for participant.
12/3/2021	Updated proxy refusal bullet to include note that the proxy should be informed that the refusal/withdrawal needs to come from the participant.
10/01/2022	Completion table updated to reflect updated standardized coding.

Review schedule:

At least every 5 years.

DA007 Guidelines and Strategies for Maximizing Follow-Up

Review Committee: Data	Start Date: 4/1/2006
Attachments: None	Last Revised Date: 2/19/2018
Forms: None	Last Reviewed Date: 2/11/2020

Introduction:

The TBI model systems have established best practices intended to maximize follow-up and suggest additional strategies that will help with locating those participants who are difficult to find and may eventually be considered lost to follow-up.

Purpose:

By outlining consistent steps that are to be performed for each TBIMS participant, the lost to follow-up rate should be lower thus maximizing follow-up.

Scope:

All TBIMS centers including the TBIMS longitudinal follow-up centers that conduct Form 2 follow-ups.

Responsibilities:

The Guidelines and Strategies for Maximizing Follow-Up should be used as the best practices for follow-up for the TBIMS.

Procedural steps:

- Attempt to follow-up should begin on the follow-up window open date.
- If the data collector cannot reach a subject after 2 weeks of attempted contact, the Best Practices methods 1-8 are to be employed until the subject is reached or until the window closes.
- Best Practice #1 can be terminated or modified if no useable phone number is available or if the person indicates that he/she should only be contacted at specific times.
- If the participant requests a mailed questionnaire, Best Practice #1 can be terminated unless it becomes clear that a mail packet will not be returned. In the latter scenario, phone calls should be re-initiated to follow-up on mail packet or determine willingness to complete phone interview.
- At the discretion of the data collector, a mail packet could be initiated if certain that the phone/address are correct and the participant is not responding to phone messages. Also could send mail packet to family member/support person, same reasoning.

- Best Practices #2-8 should be repeated at least twice during the window if useable contact information is not obtained.
- The Best Practices Methods (#1-8 listed below) are the minimum expectations for methods that are to be employed to find and interview participants.
- These methods can be applied in any sequence to best fit the circumstances of each center.
- Cases lost to follow-up prior to 7/1/2007 must have a completed Guidelines and Strategies for Maximizing Follow-Up Form kept on file at the center for every participant entered into the National Database as Lost. Cases entered into the database as lost to follow-up on or after 7/1/2007 are required to have the equivalent form completed in the database.
- The "Additional Strategies" listed on pages 4 are recommended for each site to consider as it applies to them, but are not required.

Best Practices Methods: (required)

1. **Phone Contact**
   - 4 attempts during normal business hours (at different times of the day)
   - 4 attempts during weekday evenings (on different days of the week)
   - 4 attempts during weekends
2. **Directory Assistance**
   - Call directory assistance (411) in last known city of residence, and surrounding areas, to obtain updated information about subject and contacts.
3. **Internet Sites**
   - Superpages.com, Anywho.com, theultimates.com
   - Search engines (ex., Google and Yahoo)
4. **Send Letter to Subjects and Contacts**
   - Letter to subject at last known address
   - Letter to contacts at last known address
   - Send all letters via first class mail, marked 'Forwarding & Address Correction Requested,' so that you can make note of any address changes.
5. **Hospital Information/Medical Records**
   - Check for post-discharge contact and updated information in the outpatient section of medical record.
   - Check appointment schedules, outpatient clinic lists, and/or other hospital database for new information.

- Ask social workers, clinic staff, and other hospital employees involved with the subject's care for additional or updated information.

6. **Death Search**
   - Contact Social Security Administration at (800) 772-1213
   - Local online newspaper obituary search
7. **Inmate Search**
   - County Jail
   - State Prison – Department of Corrections (See link to Online Offender Databases in the syllabus under Residence [RES])
     - Info required: full name and either SS# or DOB
   - Federal Prison System
     - (202) 307-3198
     - Call 10:30am to 4:30PM EST
     - Info required: full name, DOB, and SS#
8. **Location Services**
   - Accurint, Comserv, and/or TLO (formerly Merlin) are recommended by many sites (there is a fee involved for these services).

Additional Strategies for Maximizing Follow-Up: (Suggested)

Before Discharge from Rehabilitation Facility

- Ask participant to tell his/her contacts that the study site has been given their name, the reasons why, and that they may be contacted in the future.
- Give business cards, magnet, or pens with logo/name of site to participant and/or contacts.
- Note the participant's professional organizations (bar associations, licensures, etc.)
- Ask for a current list of healthcare providers for participant, especially primary care physician. Obtain permission/signed release forms from the subject if assistance in information gathering is needed in the future.

Hospital Contacts

- Contact billing office and/or hospital pharmacy for recent contact information and address changes.
- Work with doctors to schedule rehab appointments that will coincide with follow up windows.
- Regularly check clinic appointment schedules for opportunities to make contact with subject. Even if window is not open at the time of the clinic visit, this is a good time to confirm current contact information and just say hello.

Possible Contact Updates

- Contact Voter Registration/Electoral Registries.
- Contact Public Health Nurses in last known county of residence.
- Contact VNA (Visiting Nurse Association) or CCS (California Children's Services – participant must be 18 or under at time of injury) if available in your area.
- Check nursing homes in last known area of residence.
- Contact the Vital Statistics Department/Registry of Births, Deaths, and Marriages (there is a fee to obtain this information) http://www.vitalrec.com/

Phone/Mail Contact

- Mail reminder cards a few weeks before window opens, to let them know they will be hearing from you soon.
- Mail handwritten, hand-addressed note to participants who have not responded to phone calls or mail-outs.
- Send 'attempt to contact' letters via Certified mail.
- Ask rehab doctor for updated contact information, and/or have doctor contact via mail/phone.
- During follow up calls, ask participant if they have plans to move, or any new contact information, such as a new work, cell phone number, or email address.
- When attempting to reach participant by phone for follow up data collection, use a line with a TBI Model System Identifier, rather than using a blocked identifier (as is the case with many hospital lines).
- Have the same staff member complete all follow up calls, in the interest of building rapport and trust between the data collector and the subject. If possible, have the person who consented the subject also complete that subject's follow up.
- Generate a monthly contact call list based on injury date. For first five years the call should be six months post injury date. So, for example, if a person was injured in January, their contact call would be in the month of July. After the fifth year of participation, change the call to the month of injury, so that in "off years" the participant is called in what would be the halfway point of their window. When the list is generated, if you've had recent (within 3 months) contact with a subject, no need to call that person unless they've been difficult to track in the past.

Other methods

- Develop monthly or quarterly newsletters for distribution to all the subjects enrolled in your site. Send these via first class mail, so that they will be returned to your site with changed address information.
- Send birthday and/or holiday cards (also sent first class).

- Give gift certificates or monetary rewards for completing follow up data collection, or for notifying site of an address/phone number change.
- Discuss status of subject tracking at weekly/monthly meetings. Review call attempts, lost subjects, open and closed windows, and additional strategies for data collection.
- Call on a rainy day (especially Saturday)!

Training requirements:

Follow-up strategies will be discussed at the Data Collectors in-person conferences and is a possible topic for the quarterly data collectors' teleconferences.

Compliance:

All TBIMS centers and the TBIMS longitudinal follow-up centers are required to adhere to this procedure. The Guidelines and Strategies for Maximizing Follow-up Forms on all participants submitted to the TBIMS National Database as lost to follow-up as of 1/1/07 will be reviewed during the NDSC Quality Support Visits. The electronic version of the Guidelines and Strategies for Maximizing Follow-up Forms (pop-up window) was implemented on 07/01/2007, and as of that date, the electronic version of this form will be reviewed during NDSC Quality Support Visits.

References:

Never Say Lost: A Practical Guide for Maintaining Participant Follow-Up in Clinical Trials, 3rd edition. Pittsburgh, PA: National Surgical Adjuvant Breast and Bowel Project, Operations Center. Available as a pdf document at http://www.nsabp.pitt.edu/Never_Say_Lost.pdf.

History:

Date	Action
4/1/2006	Version used to create this SOP
9/16/2008	Transferred to SOP template and approved by SOP Review Committee
12/12/2008	Added that follow-up should start when window opens. Review approved by Planning Committee and Project Directors
10/1/2010	Added that cases lost to follow-up on or after 7/1/2007 are required to have Guidelines and Strategies for Maximizing Follow-Up data entered in the database
10/1/2013	SOP Revised to include the information from the Guidelines and Strategies for Maximizing Follow-up Form
8/21/2014	Clarification was made regarding how to complete procedural steps for required Best Practices. Statement added that Best Practices (steps 2-8) should be repeated at least twice during the window if useable contact information is obtained. Phone number for Federal Prison updated. Bullet added to

Date	Action
	Additional Strategies (generate a monthly contact call list to keep in touch with participants in between follow-up years).
2/19/2018	Added "Mail handwritten, hand-addressed note to participants who have not responded to phone calls or mail-outs." to Phone/Mail Contact strategies.
2/11/2020	SOP Reviewed

Review schedule:

At least every 5 years.

DA008 Handling Unexpected Events at Follow-up	
Review Committee: Data	Start Date: 12/03/2008
Attachments: None	Last Revised Date: 12/1/2009
Forms: None	Last Reviewed Date: 2/11/2020

Introduction:

The TBI model systems strive to ensure a continuity of process for addressing unexpected events occurring during follow-up data collection (FORM 2) for the TBIMS National Database.

Purpose:

To have a procedure in place for data collectors to provide assistance for interview participants, as appropriate, if unexpected events arise during follow-up data collection.

Scope:

Current TBIMS and Longitudinal follow-up centers that are collecting follow-up data for the TBIMS National Database.

Responsibilities:

In the process of gathering follow-up data for NDB cases, participants may describe a physical or emotional condition that could have immediate or emergent consequences, such as (but not limited to) comments reflecting a desire for harm of self or others. In such situations, appropriate steps should be taken to guard the health and welfare of the research participant and others, as needed.

Procedural steps:

Each center must establish a procedure for data collectors to employ in this situation to ensure that appropriate assistance is available to the data collector and to the research participant. The specific steps taken may be different from center to center based on the services and staff available.

Training requirements:

Each center is responsible for training data collection personnel regarding the procedure.

Compliance:

During site visits, NDSC staff will confirm that the procedure exists and that staff have been trained regarding the procedure. There is no need to file the procedure with the NDSC.

References:

None

History:

Date	Action
12/03/2008	New SOP drafted by Data Committee
08/13/2009	Approved by Data Committee
09/01/2009	Approved by SOP Committee
12/01/2009	Revisions recommended by Data Committee and approved
01/18/2010	Approved by SOP Committee
09/08/2014	SOP Reviewed
02/11/2020	SOP Reviewed

Review schedule:

At least every 5 years.

DP001 Quarterly Submission Process for Data Center	
Review Committee: NDSC	Start Date: 4/1/2009
Attachments: None	Last Revised Date: 1/15/2020
Forms: None	Last Reviewed Date: 1/15/2020

Introduction:

Provide a consistent process for completing a quarterly data submission for the TBI Model Systems National Database.

Purpose:

Outlines the steps necessary to complete a quarterly data submission.

Scope:

NDSC

Responsibilities:

NDSC Data managers

Procedural steps:

Below are listed the step that the NDSC will take to complete a Quarterly data submission.

1. Notice of submission will occur at least one week prior to the submission date (1/15, 3/31,6/30, 9/30). Notification will go out through the Data Collectors listserv.
2. Remove access to data entry. This will occur at 5:00 PM PST to allow a full working day for west coast centers.
3. Remove any test data from all tables (quarterly cleanup.sql)
    a. Center > 31
    b. Subject ID > 77777
    c. TBIID cause is null
4. Perform Data checks for each center on the following data:
    a. Screening
    b. Cases overdue (populate database with overdue cases listed as ‘Lost’) (cases Overdue for paste.sql)
    c. Error Checks
5. Create and publish the following static reports:

   a. Quarterly Report
   b. Target Analysis
      i. Email individual center results
   c. Missing Data Report (rolling year)
   d. Missing Data Analysis (rolling year)
   e. Missing Data Completeness (rolling year)
   f. Payment Reports (for Follow-Up centers)
6. Link documents to the quick links section of the home page
7. Archive previous reports in the "Published Reports" members section
8. Archive data collection forms (StaticFiles/DataForms) if new version
9. Move new versions of data collection forms to SOP directory
10. Archive the following data tables: (create archive.sql)
   a. Master
   b. ArchiveMod1
   c. ArchiveMod2
   d. ArchiveBenchmark
   e. Screening
   f. vw_mod1_with_calculations
   g. vw_mod2_with_calculations
   h. All modules
11. Remove cases with errors from the newly created archives
   a. Create views in Archive to show non error cases
   b. Generate list of cases with errors and give to analyst (to change the longitudinal dataset)
12. Create SPSS Copies of all the data with and without PHI to be used as analysis files for the quarter from the newly created views for data without errors.
13. Enter in new version numbers into SQL
14. Update the Data Dictionary on the "live" site
15. Update new code (ASPX, C#, javascript, Angular) from the test site to the "live" site
16. Update Crystal reports from the test site to the "live" site (reset database connections as appropriate)
17. Test the live web site:
   a. View each updated page

   b. Enter a test Form 1 case
   c. Enter a test Form 2 case
   d. Enter a test Screening case
   e. Run each updated report
18. Enable Data Entry
19. Notify Centers of Data Entry status

Training requirements:

None

Compliance:

All NDSC Data Managers are responsible for adhering to this policy and its procedures.

References:

None

History:

Date	Action
4/1/2009	New policy developed
09/17/2011	Last reviewed date
01/15/2020	Reviewed in full and edited to reflect updated procedures

Review Schedule:

Bi-annually

DP002 Quarterly Submission Process for TBIMS Centers	
Review Committee: NDSC	Start Date: 3/05/2011
Attachments: Submission Checklist	Last Revised Date: 4/12/2021
Forms: None	Last Reviewed Date: 1/15/2020

Introduction:

On a quarterly basis the NDSC is responsible for generating TBIMS reports, and preparing datasets for statistical analysis. The NDSC has prepared the following guidelines to ensure accuracy of reports, data integrity, and timeliness of delivery.

Purpose:

Outlines the steps necessary to complete a quarterly data submission.

Scope:

All TBIMS Centers, longitudinal follow-up centers, and the NDSC.

Responsibilities:

All TBIMS Center Data Managers.

Procedural steps:

Submission of data to the NDSC happens quarterly on the following dates: 1/15, 3/31, 6/30, and 9/30. At 5:00 p.m. Pacific Time on the submission date, access to the data entry forms will be disabled. No changes or additions of data will be allowed without the consent of the NDSC. If a center is unable to complete the submission by the deadline, they risk not having their data included in the quarterly reports. Exceptions to this will be handled on a case-by-case basis by the NDSC staff. If for any reason you are unable to meet the deadline you should contact the NDSC immediately.

Below is a list of the steps that each center should take prior to the submission deadline to complete a quarterly data submission.

1. All data should be entered into the TBIMS National Database.
2. Verify that SOP DQ001 - *Data Quality Guidelines* have been followed.
    a. Complete 10% data entry checks on Form 1 and Form 2.
    b. Fix all errors identified on the Error Analysis report.
    c. Run both Inter-Form and Intra-Form Consistency Reports for the given quarter, and review all inconsistencies. Resolve all inconsistencies where an error has occurred, and disregard any inconsistencies where an error has not occurred.

d. Review the Form 1 and Form 2 Missing Analysis Reports for the given quarter and verify missing data points listed by Subject ID.

e. Run the Cases Past Due report. Update any cases on this report as lost as appropriate, making sure to complete the ”Lost” tab in the Form 2 data entry screen.

f. Run the Lost Cases: Guidelines and Strategies report for the given quarter and verify that all lost cases have been updated by completing the “Lost” tab.

3. For determining which cases are due for submission, refer to the following table and footnotes:

Submission Date:	Cases Due:		Corresponding Report:
01/15/(CY)	*07/01/(PY) to 09/30/(PY)*	*Quarter 3 (PY)*	*Quarter 4 (PY)*
03/31/(CY)	*10/01/(PY) to 12/31/(PY)*	*Quarter 4 (PY)*	*Quarter 1 (CY)*
06/30/(CY)	*01/01/(CY) to 03/31/(CY)*	*Quarter 1 (CY)*	*Quarter 2 (CY)*
09/30/(CY)	*04/01/(CY) to 06/30/(CY)*	*Quarter 2 (CY)*	*Quarter 3 (CY)*

(CY)=Current Year, (PY)=Previous Year

Form 1: Include cases with rehab discharge dates in given range

Form 2: Include cases with window closing dates in given range

Form 1 & Form 2 cases may be entered early, but will not be reflected in ‘In Qtr’/‘In Yr’ report statistics until due

Training requirements:

None

Compliance:

All TBIMS Data Managers and Collectors will comply with this policy and its procedures.

References:

None

History:

Date	Action
3/5/2011	New policy developed
10/1/2012	Revised policy to reference rehab discharge dates as key to cases due
1/15/2020	Reviewed in full and revised to reflect new data entry procedures
4/12/2021	Updated “Missing Data” report references to “Missing Data Analysis”, Removed instruction to run “Quarterly Report”

Review Schedule:

Bi-annually

Submission Checklist

Data Entry

- ☐ Screening data entry up-to-date
- ☐ Form 1 data entry completed
    - Error check completed on last tab of data entry and any errors corrected
- ☐ Form 2 data entry completed
    - Error check completed on last tab of data entry and any errors corrected

Data Quality Guidelines Requirements

- ☐ All staff certifications up-to-date (FIM, DRS, Form 1, CT, Cultural)
- ☐ Form 1 Re-Abstraction (1 case; if errors, 1 more case)
- ☐ Form 2 Interview (completed annually: listen in, code and compare)
- ☐ Data Entry (10% checked for accuracy: if errors all forms to be verified)
    - Form 1
    - Form 2
- ☐ Error Analysis report run and all errors fixed
- ☐ Inter-Form Consistency report run and all items reviewed.
    - Items corrected where error has occurred
    - Remaining items verified for accuracy
- ☐ Intra-Form Consistency report run
    - Items corrected where error has occurred
    - Remaining items verified for accuracy
- ☐ Form 1 and Form 2 Missing Analysis reports reviewed for accuracy
- ☐ Cases Past Due report run
    - Lost cases have been entered as “lost”. (Any cases left on this report at time of submission will be automatically coded as “lost”.)
- ☐ Lost Cases: Guidelines & Strategies report run and reviewed for completeness

DP003 Editing, Entering, and Submitting Old Data	
Review Committee: NDSC	Start Date: 04/01/2004
Attachments: None	Last Revised Date: 7/1/2010
Forms: None	Last Reviewed Date: 11/19/2019

Introduction:

Editing, entering, and submitting old data poses several challenges within the context of maintaining a dynamic national database. First, any large-scale updates may undermine the reproducibility of prior analyses. Additionally, when core variables are discontinued and archived, they can no longer be accessed for entry or editing via the online data entry program.

Purpose:

To institute a standardized policy for editing, entering, and submitting old data.

Scope:

All TBIMS Centers, TBIMS Follow-up Centers, and the NDSC.

Responsibilities:

All TBIMS staff that edit or enter new data for existing cases are responsible for adhering to the following procedural steps.

Procedural steps:

Any data entered into the TBI National Database at the time of a quarterly data submission is considered old (or existing) data once the data submission deadline has elapsed. At the time of a data submission, datasets are archived by the NDSC and may be distributed to Model Systems investigators for analyses.

Editing old data: Model Systems centers may edit old data using the online data entry program at any time. Existing data may be edited to correct errors identified during any stage of the data quality monitoring process.

Entering old data: Model Systems centers may enter data for previously missing or unknown variables, or update overdue cases using the online data entry program at any time. Updated data will not be reflected in any NDSC reports that have already been disseminated or, at the discretion of the NDSC, are currently in progress.

Submitting old data: Data updates for existing cases will automatically be submitted to the NDSC at the time of the next scheduled data submission. Some data updates may be reflected in subsequent reports published by the NDSC (i.e., cases with missing data on the semi-annual missing data report that are updated prior to publication of the annual missing data report will not be counted toward missing data rates; cases overdue that are entered prior to publication of the next quarterly report will be counted toward ‘in year’ and ‘overall’ follow-up rates).

When editing, entering, and submitting old data:

- Care should be taken to ensure that old data codes match current codes in the database.
- Data checks should be performed on all edited cases to ensure changes have not resulted in any new errors.
- If there are more than a few small changes, the NDSC should be notified of the changes prior to the next scheduled data submission deadline. (Changes made to correct errors listed on NDSC reports do not need to be reported to the NDSC.)
- Upon receiving notification of systematic changes to old data, the NDSC will notify all individuals or parties who have requested datasets within the past 4 quarters likely to be impacted. Changes of an exceptional nature will be handled on a case-by-case basis, should they be encountered.
- To edit or enter data for archived variables that cannot be accessed from the online data entry program, Model Systems centers should provide the NDSC with a list of required updates. The NDSC will either make the required updates for the center, or arrange other methods for the center to provide updates.

Training requirements:

Staff responsible for entering, and editing data in the TBI National Database should be familiar with the contents of this SOP.

Compliance:

All centers utilizing the TBI Model Systems National Database are responsible for adhering to this policy and its procedures.

References:

None

History:

Date	Action
4/1/2004	Version used to create this SOP
9/16/2008	Transferred to SOP template and approved by SOP Review Committee
6/16/2009	Changed wording of SOP to reflect new Web based data entry
7/1/2010	Revised
11/19/2019	Full review completed by NDSC

Review Schedule:

At least every 5 years.

DP004 Obtaining and Coding Cause of Death in the TBIMS National Database

Review Committee: Data	Start Date: 3/25/2013
Attachments: None	Last Revised Date: 1/15/2017
Forms: None	Last Reviewed Date: 11/19/2019

Introduction:

Accurate coding of cause of death through the use of final death certificates is important to obtain valid mortality data for studies of individuals with TBI.

Purpose:

To establish standards for transmitting/storing death certificates and coding cause of death in the TBIMS National Database by the NDSC.

Scope:

All TBIMS centers including the TBIMS longitudinal follow-up centers that conduct FORM 2 follow-ups, and the NDSC.

Responsibilities:

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

Procedural steps:

1. Upon receiving notice that a participant in the TBIMS has expired, each center must attempt to obtain a valid and final death certificate issued by the state. Regardless of when the information is received, the data collector should classify the participant as deceased in the next follow-up period for that individual (e.g., if it is identified that a person expired 3 years post injury, then a Year 5 Form 2 should be submitted and the date of death recorded). If the person expires during inpatient rehabilitation the death should be recorded on the Form 1.
2. To obtain a final copy of the death certificate, write or go to the vital statistics office in the State or area where the death occurred (a complete list can be found at the CDC website (http://www.cdc.gov/nchs/w2w.htm). Addresses and fees are given for each certificate in the State or area concerned.
3. To ensure that you receive exactly what you request and that your request is completed expeditiously, follow the steps outlined below:
    - For all requests, make check or money order payable to the identified office, in the correct amount for the number of certificates requested. Sending cash is not recommended because the office cannot refund cash lost in transit.

- Because all fees are subject to change, a telephone number is included in the information for each State to call and verify the current fee.
- States provide their home webpage address to obtain current information.
- Type or print all names and addresses in the letter.
- Provide all the information requested, if available, such as:
  - Full name of person whose certificate is requested.
  - Sex.
  - Parents' names, including maiden name of mother.
  - Month, day, and year of death.
  - Place of death (city or town, county, and State; and name of hospital, if known).
  - Purpose for which certificate is needed.
  - Relationship to person whose record is requested.
  - Your daytime telephone number with area code.

4. Upon receipt of the death certificate, the center should retain the original and make a copy to be redacted and sent to the NDSC. The following information should be redacted from the copy of the certificate sent to the NDSC:
   - Name
   - Address
   - Social security number
   - Relative's names and information
   - State death certificate number
5. The redacted copy of the death certificate sent to the NDSC should include:
   - Date of birth
   - Date of death
   - All final causes of death
   - Manner of death
   - Date of onset of diagnoses leading to death
   - Time and place of death
   - Description of death by coroner
   - Whether an autopsy was performed
   - Participant's TBI model system identification number.
6. The redacted copy of the death certificate should then be scanned to a pdf file and uploaded to the TBIMS National Database website under the MEMBERS – UPLOAD section of the TBINDSC website (www.tbindsc.org).
7. After uploading the death certificate to the NDSC, email a copy of the death certificate invoice to Donna Wolff [dwolff@craighospital.org] at the NDSC and your center will be reimbursed for the cost of obtaining the death certificate.

TBIMS NDSC will be responsible for the following upon receipt of the death certificate:

1. Storing an electronic copy of the death certificate in a secure server at the NDSC as user-ID and password protected computer files.
2. Coding the causes of death using the using the instructions below.
3. Verifying the date of birth on the death certificate matches the date of birth for the participant in the national database.

4. Verifying the date of death on the death certificate matches the date of death for the participant in the national database.
5. Adding a pdf sticky note/comment box inserted in the pdf file of the death certificate with the cause of death codes.
6. Entering the cause of death codes into the National Database.

All coding and entering into the national database of the cause of death data will occur no later than 1 quarter after the NDSC receives the death certificate. At the beginning of each quarter the NDSC will distribute a list of all cases to each center which have been coded as having died in the national database but a death certificate has not been submitted to the NDSC.

Below are the steps that the NDSC will take to ensure confidentiality and security of death certificates maintained by the NDSC:

1. Death Certificates will be destroyed in accordance with Craig Hospital's disposal procedures. Identifiable information will be disposed of in a confidential manner upon the project's completion or within five years of the date of the original release, whichever occurs first, unless an extension is requested of and approved by the corresponding health department from which the death certificate was obtained. Identifiable information includes: certificate numbers, OCME numbers, names, exact dates, Social Security numbers, addresses, census tracts/blocks, institution names, some exact measure (e.g. birth weight), write-in items, and any other information that may identify an individual. Anything that contains identifiable information will be destroyed. This includes original certificate copies, computer files and/or their abstracts and any reproductions. Linkages to other datasets with identifiable information will also be destroyed.
2. As a matter of daily operations, individual worksheets or other materials containing patient information, that are not to be kept as part of the research project file, are deposited into locked shredding containers.

GUIDELINES FOR CODING PRIMARY CAUSE OF DEATH (NDSC Responsibility)

In general, death certificates will have a line that documents the immediate cause of death followed by two or three lines under the heading "due to or as a consequence of." There will also be a line to document "other significant conditions."

A. As a general rule, the primary cause of death will be the cause entered alone on the lowest line of the "due to or as a consequence of" sequence unless it is unlikely that this condition gave rise to all the other conditions listed above it. *If you are uncertain about this, consult your center's medical professionals. An "Other significant condition" would be coded as a secondary cause of death unless it can be specifically linked to the causes listed above it, in which case it might be included in a combined primary cause of death. Any mention of traumatic brain injury, head trauma, etc. (including *late effects of TBI)* should be ignored **unless it is a new injury (See F)*.

For example, consider the following cases:

1.	Immediate cause:	Cardiac arrest	427.5
	Due to or as a consequence of:		
	Due to or as a consequence of:		

Unless additional information can be acquired, select cardiac arrest (427.5) because, unfortunately, it is the only option available.

2.

Immediate cause:	Cardiorespiratory arrest	427.5
Due to or as a consequence of:	Pneumonia	486
Due to or as a consequence of:		

Select pneumonia (486) since it led to the cardiorespiratory arrest.

3.

Immediate cause:	Cardiorespiratory arrest	427.5
Due to or as a consequence of:	Septicemia	038.9
Due to or as a consequence of:	Pneumonia	486

Select pneumonia (486) because it led to the other conditions. List septicemia as a secondary cause.

4.

Immediate cause:	Cardiorespiratory arrest	427.5
Due to or as a consequence of:	Arteriosclerosis	440.9
Due to or as a consequence of:	Late effect of intracranial Injury	907.0

Select arteriosclerosis (440.9) and ignore the reference to TBI.

5.

Immediate cause:	Cardiorespiratory arrest	427.5
Due to or as a consequence of:	Septicemia	038.9
Due to or as a consequence of:	Renal failure	586

Select septicemia (038.9) because renal failure (which would ordinarily have been chosen) cannot cause septicemia. List renal failure as a secondary cause.

6.

Immediate cause:	Arteriosclerosis	440.9
Due to or as a consequence of:	Pneumonia	486
Due to or as a consequence of:		

Select arteriosclerosis (440.9) because pneumonia (which would ordinarily have been chosen) cannot cause arteriosclerosis. List pneumonia as a secondary cause.

7.

Immediate cause:	Cardiac arrest	427.5
Due to or as a consequence of:	Hemorrhage	459.0
Due to or as a consequence of:		
Other significant conditions:	Peptic ulcer	533.4

Unless there is specific evidence indicating the hemorrhage was not associated with the peptic ulcer, select peptic ulcer with hemorrhage (533.4) because hemorrhage (which would ordinarily have been chosen) can be linked with peptic ulcer to identify a more specific condition. The important question is whether this death is better classified as resulting from a disease of the digestive system or a disease of veins and lymphatics. Certainly, the former seems more appropriate given the available information.

8.

Immediate cause:	Pernicious anemia	281.0
Due to or as a consequence of:	Cerebral hemorrhage	431
Due to or as a consequence of:	Arteriosclerosis	440.9

Select pernicious anemia (281.0). Although arteriosclerosis can cause a cerebral hemorrhage, it cannot cause pernicious anemia. Cerebral hemorrhage also cannot cause pernicious anemia. Therefore, with no apparent causal sequence leading directly to the immediate cause of death, the immediate cause is selected as the primary cause of death. The others should be listed as secondary causes.

B. In general, ill-defined conditions should not be selected as the primary cause of death unless no alternative exists. *(For exception – see H.)

For example:

1.	Immediate cause:	Myocardial infarction	410.9
	Due to or as a consequence of:	Tachycardia	785.0
	Due to or as a consequence of:		

Select myocardial infarction (410.9) because tachycardia (which would ordinarily have been chosen) is considered a "symptom or ill-defined condition." Tachycardia can be listed as a secondary cause of death.

C. In general, trivial conditions should be ignored. If death is the result of an adverse reaction to treatment for a trivial condition (such as renal failure resulting from taking aspirin for recurrent migraines), then code the adverse reaction as the primary cause of death. If the trivial condition is not reported as the cause of a more serious complication and a more serious unrelated condition is reported, then code the more serious condition as the primary cause of death.

For example:

1.	Immediate cause:	Congenital anomaly of eye	743.9
	Due to or as a consequence of:	Congenital heart disease	746.9
	Due to or as a consequence of:		

Select congenital heart disease (746.9) even though it cannot cause a congenital anomaly of the eye because the latter is considered a trivial condition unlikely by itself to cause death.

D. When the normal selection process results in choosing a condition which is described only in general terms and a related cause is also reported which provides more precise information about the system or nature of the chosen condition, reselect the more informative cause as the primary cause of death.

For example:

1.	Immediate cause:	Cerebral thrombosis	434.0
	Due to or as a consequence of:	Cerebrovascular accident	436
	Due to or as a consequence of:		

Select cerebral thrombosis (434.0) because it is more informative and precise than cerebrovascular accident (which would ordinarily have been chosen). Cerebrovascular accident can be listed as a secondary cause.

2.	Immediate cause:	Pyelonephritis	590.8
	Due to or as a consequence of:	Kidney stone	592.0
	Due to or as a consequence of:	Renal disease	593.9

Select kidney stone (592.0). Both kidney stone and pyelonephritis are more specific than renal disease, but kidney stone would have been selected if renal disease had not been listed on the certificate. Therefore, it is preferred over pyelonephritis, which can be listed as a secondary cause of death along with renal disease.

E. It is important to consider the interval between onset and death for each condition specified on the death certificate. Acute conditions that occurred a protracted time prior to death probably will not be the primary cause of death.

For example:

Immediate cause:	Congestive heart failure (3 mo)	428.0
Due to or as a consequence of:	Pneumonia (1year)	486
Due to or as a consequence of:		

Select congestive heart failure (428.0) because the episode of pneumonia occurred a long time before the patient died as well as long before the symptomatic heart disease began.

F. The use of E codes is very important because it is the only way to distinguish accidents, suicides and homicides from each other as well as from natural causes of death. However, E codes should only be used to reflect injuries that occur after the original TBI producing event. *<u>If an injury or poisoning code is reported (800-999), it should always also have an E-code (E800-E999) with it.</u> If an E code is appropriate, it will always be treated as the primary cause of death.

The distinction between accident, suicide and homicide can be found in a separate box on the death certificate below the list of causes.

G. When the death certificate does not provide adequate information (for example when the only cause of death listed is "head trauma"), which refers to the original injury, code the cause of death as unknown.

H. *For a death due to seizure or seizure disorder, use the seizure code 780.39 as opposed to the epilepsy codes 345.90 & 345.91. Someone who dies of Post-Traumatic Seizures should be coded as cause death due to seizure.

I. *When the death certificate reports the cause of death due to cancer/neoplasm, if a site of the cancer is given (e.g., lung cancer) assume this to be the primary site, if not otherwise specified.

J. *If the death certificate lists several “Other significant conditions” or “Secondary causes”, try to select from a different diagnosis grouping, for your secondary code, to provide more information upon analysis.”

For example:

1.	Immediate Cause:	Adult Respiratory Distress Syndrome	518.4
	Due to or as a consequence of:	Streptococcal Pneumonia	481

Other significant conditions:	Pseudomonas Sepsis	038.43
	Acute Glomerulonephritis	584.9

Select Streptococcal Pneumonia (481) because it led to the other conditions. List the acute Glomerulonephritis as your secondary code as it provides a different diagnosis grouping.

Adapted from the Spinal Cord Injury Model Systems

Updated 04/01/2011

Updated 04/09/2004

Implemented 10/1/2004

Training requirements:

Staff responsible for the Form 1 and Form 2 data collection for the TBIMS national database should be familiar with this procedure. On-going training will be conducted by quarterly data collector teleconferences and in-person data collectors' meetings.

Compliance:

All centers collecting data on participants in the TBI Model Systems National Database and the NDSC are responsible for adhering to this procedure.

References:

History:

Date	Action
3/25/2013	New policy developed and approved by Project Directors
1/15/2017	Added section addressing destruction of Death Certificates Added "Guidelines for Coding Primary Cause of Death" section (was formerly a separate linked document under "Cause of Death" syllabus page).
11/19/2019	Full review completed by the NDSC

Review schedule:

At least every 5 years.

DP005 Notification of Staff Changes	
Review Committee: NDSC	Start Date: 10/28/2008
Attachments: None	Last Revised Date: 10/28/2008
Forms: None	Last Reviewed Date: 11/19/2019

Introduction:

With the adoption of the web-based entry and reporting capabilities, it is imperative that the NDSC be notified of all staff changes (additions, changes, removal) from each center within two working days so that the NDSC can alter the data access privileges for that individual. While notifications of additions to the TBIMS should occur as needed, notification for removal of a person, or a change in role function from the TBIMS is critical for data security.

Purpose:

To assure that only current TBIMS staff have access to data and reports accessed from the Internet.

Scope:

All current TBIMS Centers

Responsibilities:

All current TBIMS Project Directors and/or Data Managers

Procedural steps:

As staff changes at a center, Project Directors or Data Managers must notify the NDSC of the change as soon as possible. The notification can be either a phone call, email, or fax. Once the change has taken place, an email to the PD will confirm the change.

Training requirements:

None

Compliance:

All collaborating centers utilizing the TBIMS National Database are responsible for adhering to this policy and its procedures.

References:

None

History:

Date	Action
10/28/2008	New policy developed
11/17/2008	Approved by SOP Review Committee
12/12/2008	Approved by Planning Committee and Project Directors
11/19/2019	Full review completed by the NDSC

Review schedule:

Bi-annually

DQ001 Data Quality Guidelines and Principal Investigator Verification of Compliance

Review Committee: Data	Start Date: 10/28/2008
Attachments: None	Last Revised Date: 9/12/2022
Forms: PI Verification of Compliance with Data Quality Guidelines	Last Reviewed Date: 8/27/2020

Introduction:

The TBIMS have established data quality guidelines and strategies to ensure that data is being collected the same way throughout the TBIMS.

Purpose:

Through standardized practices for data quality, integrity of data will be preserved.

Scope:

All TBIMS centers and TBIMS longitudinal follow-up centers that participate in data collection for the TBIMS National Database.

Responsibilities:

Each TBIMS Project Director is responsible for the integrity of data being collected within his/her center. The Project Director is also responsible for tracking and assuring that the Data Quality Guidelines outlined below are followed in his/her center. It is recommended that each TBIMS maintain a log documenting that these guidelines are being followed.

Procedural Steps:

1. **FIM® Instrument:** It is the responsibility of each center to assure that all staff who perform FIM® assessments and those performing the data quality checks (Form 1 and Form 2) are trained/certified and training/certification is repeated bi-annually for the duration of the time that they collect data/assess patients for the TBIMS National Database. FIM® training and certification is to be completed with the ITHealth DVDs provided by the NDSC.
2. **Disability Rating Scale (DRS):** It is the responsibility of each center to assure that all staff who perform DRS ratings and those performing the data quality checks for Form 1 are trained and certified through the website at "www.tbims.org/combi/drs/". All staff should be re-certified bi-annually.
3. **Pre-Injury History Data:** The Pre-Injury History should be used to collect relevant data for the TBIMS National Database Form 1. Exact wording of questions is provided. The Pre-Injury History form is available on the NDSC website. Centers should not be using their own data collection methods or forms.

4. **Intracranial CT Diagnosis:** TBIMS staff coding the CT Diagnosis data collection should be certified. Certification materials can be obtained from the National Data and Statistical Center. The Database Syllabus contains the CT data collection form with guidelines. Staff coding the CT forms need to be recertified every 10 years.
5. **Data Collected from Medical Charts:** Each center will have an independent certified staff member re-abstract the entire Form 1 on one case entered each quarter. If any errors in coding are found they should be corrected and another one of the cases for the quarter should be re-abstracted and any errors corrected. This should be done prior to each quarterly submission deadline (e.g., March 31, June 30, September 30, and January 15).
6. **Form 1 Certification:** Each center will have the staff responsible for completion of the Form 1 data collection for the TBIMS National Database complete the Form 1 Certification bi-annually. For new employees, contact the NDSC for materials to complete the certification process, otherwise, the NDSC will notify centers when to complete the bi-annual process.
7. **Cultural Certification:** It is the responsibility of each center to assure that all staff responsible for enrollment, Form 1 Pre-Injury History collection or Form 2 Data collection complete the Cultural Certification provided in the "Cultural" section under the Members tab on the TBINDSC website.
8. **Data Entry:** Data entry for a random sample of at least 10% of Form 1s will be verified by having a different staff member compare the complete data collection form to the data entered into the database. If any errors are detected, all forms should be verified. This should be done prior to each quarterly submission deadline. The same procedure will be used for Form 2 data entry if paper forms are used.
9. **Data Errors Discovered During Analysis:** All data errors (or questionable data) identified during any analysis of data in the national database, by any center staff, will be reported to the NDSC for distribution and correction by the other centers.
10. **Data Collected by Interview:** Each center, on an annual basis, should have another center staff person sit in on an interview (via phone, recording, or in-person) and code and compare a Form 2 for each Form 2 data collector. If any errors are found, they should be corrected and another interview should be coded by the independent staff person.
11. **Error Analysis Report:** Each center should review the database Error Analysis report after all data entry is completed for a quarterly submission deadline and attempt to correct all errors before that quarterly deadline. All cases containing errors at the time of submission will be excluded from distributed datasets.
12. **Coding Consistency:** Each center should run the Inter-form and Intra-form coding consistency reports after all data entry tasks have been completed for a quarterly submission deadline and review all inconsistencies before that quarterly deadline. Centers should attempt to correct all inconsistencies where an error has occurred, and disregard any inconsistencies where an error has not occurred.
13. **Missing Data Reports:** Each center should run the database Form 1 and Form 2 Missing Analysis reports after all data entry is completed for a quarterly submission deadline and attempt to complete all missing data before the quarterly deadline.

14. **Screening Analysis Report:** Each center should verify that screening data entry is kept up to date throughout the quarter and prior to each quarterly submission deadline.
15. **Form 2's Overdue:** Each center should run the database Form 2 Cases Past Due report after all data entry is completed for a quarterly submission deadline and complete a Form 2 for any cases appearing on the list as past due. If no information is available on the participant, complete the Form 2 considering the participant as lost to follow-up. If any Form 2s are overdue for any quarterly submission deadline, they will be considered lost to follow-up in the calculation of follow-up rates for the data quality targets.
16. **Best Practices for Follow-up:** Each center should complete the "Lost" tab in the database for every participant that is submitted to the national database as lost to follow-up (that is either they could not be located or they did not respond to contact) to assure that all best practices for follow-up have been completed. The Lost Cases: Guidelines and Strategies report should then be run to verify that each lost case has been updated.
17. **Data Quality Targets:** Each center should attempt to meet the Data Quality Targets established by the TBIMS. Those targets are: 1) annually enroll the projected number of participants stated in their grant proposal; 2) enroll 80% of eligible participants each quarter and year; 3) successfully follow 90% of participants for the Form 2 year 1 and year 2 follow-ups each quarter and year (successful follow-up = those followed, expired or incarcerated); 4) successfully follow 80% of participants for the Form 2 year 5,10, 15, etc. follow-ups each quarter and year; 5) maintain less than 10% missing data on all Form 1 and Form 2 variables each year.
18. **Data Integrity Pledge:** Each center should ensure that all TBIMS staff with data collection or data management duties, including screening and consenting sign the Data Integrity Pledge annually. Project Directors do not need to sign.
19. **Guidelines Sign-off by Project Directors:** On an annual basis, each center Project Director should submit a signed copy of this SOP to the NDSC, to indicate that these guidelines are being followed within his/her center. All signed guidelines will be archived by the NDSC.

Training requirements:

Data quality will be a continual topic of discussion both at the Project Directors Conference as well as Data Collectors in person conferences and quarterly data collector's teleconferences.

Compliance:

All TBIMS centers will be asked to discuss data quality procedures conducted at their center with the NDSC during quality support visits.

References:

None

History:

Date	Action
10/28/2008	Completely revised version from data committee used to create this SOP approved by Data Committee
11/01/2008	Transferred to SOP template
11/17/2008	Approved by SOP Review Committee
12/12/2008	Approved by Planning Committee and Project Directors
07/01/2009	Clarified what is considered "lost" for #16
10/01/2009	Clarified that a person conducting the re-abstraction should be certified
10/01/2009	Change re-abstraction rate from 10% to just one
10/01/2011	Removed item that discussed correcting errors identified by the NDSC prior to each quarterly data submission redundant with Error Reports item (#10)
10/01/2011	Eliminated requirement for having an independent staff member review 10% of data collection forms for coding consistency
10/01/2011	Added requirement for running coding consistency reports and reviewing all inconsistencies (#11)
01/01/2013	Updated #3 - Pre-Morbid to Pre-Injury; Updated #4 CT certification instructions to contact the NDSC instead of Santa Clara
04/01/2014	Updated #10 to include "All cases containing errors at the time of submission will be excluded from distributed datasets."
08/21/2014	Removed statement that the Northern California TBIMS (Santa Clara Valley Medical Center) sends out reminders for DRS certification.
11/22/2016	Updated #4 to include certification requirement of every 10 years
11/22/2016	Added ITHealthTrack to method of FIM certification
11/22/2016	Change DRS certification to be data collectors and data quality checkers for Form1
10/01/2019	Added Cultural Certification requirement.
08/27/2020	Added Data Integrity Pledge requirement. Updated ITHealthTrack as the method of FIM certification. Updated instructions for Form 2 data entry checks.
04/09/2021	Updated Enrollment Report to Screening Analysis Report
04/09/2021	Removed Quarterly Report bullet

Date	Action
09/08/2022	Updated to reflect newer report names
09/12/2022	Removed “Interview” and “Questionnaire” from PreInjury items

Review Schedule:

At least every 5 years.

Data Quality Guidelines and Principal Investigator Verification of Compliance Form

Each TBIMS Project Director is responsible for the integrity of data being collected within his/her center. The Project Director is also responsible for tracking and assuring that the Data Quality Guidelines outlined below are followed in his/her center. Each TBIMS maintain a log documenting that these guidelines are being followed. On an annual basis, each center Project Director must submit a signed copy of this form to the NDSC, to indicate that these guidelines are being followed within his/her center. All signed guidelines will be archived by the NDSC.

1. **FIM® Instrument:** It is the responsibility of each center to assure that all staff who perform FIM® assessments and those performing the data quality checks (Form 1 and Form 2) are trained/certified and training/certification is repeated bi-annually for the duration of the time that they collect data/assess patients for the TBIMS National Database. FIM® training and certification is to be completed with the ITHealth DVDs provided by the NDSC.
2. **Disability Rating Scale (DRS):** It is the responsibility of each center to assure that all staff who perform DRS ratings and those performing the data quality checks for Form 1 are trained and certified through the website at "www.tbims.org/combi/drs/". All staff should be re-certified bi-annually.
3. **Pre-Injury History Data:** The Pre-Injury History should be used to collect relevant data for the TBIMS National Database Form 1. Exact wording of questions is provided. The Pre-Injury History form is available on the NDSC website. Centers should not be using their own data collection methods or forms.
4. **Intracranial CT Diagnosis:** TBIMS staff coding the CT Diagnosis data collection should be certified. Certification materials can be obtained from the National Data and Statistical Center. The Database Syllabus contains the CT data collection form with guidelines. Staff coding the CT forms need to be recertified every 10 years.
5. **Data Collected from Medical Charts:** Each center will have an independent certified staff member re-abstract the entire Form 1 on one case entered each quarter. If any errors in coding are found they should be corrected and another one of the cases for the quarter should be re-abstracted and any errors corrected. This should be done prior to each quarterly submission deadline (e.g., March 31, June 30, September 30, and January 15).
6. **Form 1 Certification:** Each center will have the staff responsible for completion of the Form 1 data collection for the TBIMS National Database complete the Form 1 Certification bi-annually. For new employees, contact the NDSC for materials to complete the certification process, otherwise, the NDSC will notify centers when to complete the bi-annual process.
7. **Cultural Certification:** It is the responsibility of each center to assure that all staff responsible for enrollment, Form 1 Pre-Injury History collection or Form 2 Data collection complete the Cultural Certification provided in the "Cultural" section under the Members tab on the TBINDSC website.

8. **Data Entry:** Data entry for a random sample of at least 10% of Form 1s will be verified by having a different staff member compare the complete data collection form to the data entered into the database. If any errors are detected, all forms should be verified. This should be done prior to each quarterly submission deadline. The same procedure will be used for Form 2 data entry if paper forms are used.
9. **Data Errors Discovered During Analysis:** All data errors (or questionable data) identified during any analysis of data in the national database, by any center staff, will be reported to the NDSC for distribution and correction by the other centers.
10. **Data Collected by Interview:** Each center, on an annual basis, should have another center staff person sit in on an interview (via phone, recording, or in-person) and code and compare a Form 2 for each Form 2 data collector. If any errors are found, they should be corrected and another interview should be coded by the independent staff person.
11. **Error Analysis Report:** Each center should review the database Error Analysis report after all data entry is completed for a quarterly submission deadline and attempt to correct all errors before that quarterly deadline. All cases containing errors at the time of submission will be excluded from distributed datasets.
12. **Coding Consistency:** Each center should run the Inter-form and Intra-form coding consistency reports after all data entry tasks have been completed for a quarterly submission deadline and review all inconsistencies before that quarterly deadline. Centers should attempt to correct all inconsistencies where an error has occurred, and disregard any inconsistencies where an error has not occurred.
13. **Missing Data Reports:** Each center should run the database Form 1 and Form 2 Missing Analysis reports after all data entry is completed for a quarterly submission deadline and attempt to complete all missing data before the quarterly deadline.
14. **Screening Analysis Report:** Each center should verify that screening data entry is kept up to date throughout the quarter and prior to each quarterly submission deadline.
15. **Form 2's Overdue:** Each center should run the database Form 2 Cases Past Due report after all data entry is completed for a quarterly submission deadline and complete a Form 2 for any cases appearing on the list as past due. If no information is available on the participant, complete the Form 2 considering the participant as lost to follow-up. If any Form 2s are overdue for any quarterly submission deadline, they will be considered lost to follow-up in the calculation of follow-up rates for the data quality targets.
16. **Best Practices for Follow-up:** Each center should complete the "Lost" tab in the database for every participant that is submitted to the national database as lost to follow-up (that is either they could not be located or they did not respond to contact) to assure that all best practices for follow-up have been completed. The Lost Cases: Guidelines and Strategies report should then be run to verify that each lost case has been updated.
17. **Data Quality Targets:** Each center should attempt to meet the Data Quality Targets established by the TBIMS. Those targets are: 1) annually enroll the projected number of participants stated in their grant proposal; 2) enroll 80% of eligible participants each quarter and year; 3) successfully follow 90% of participants for the Form 2 year 1 and year 2 follow-ups each quarter and year (successful follow-up = those followed, expired or incarcerated); 4)

successfully follow 80% of participants for the Form 2 year 5,10, 15, etc. follow-ups each quarter and year; 5) maintain less than 10% missing data on all Form 1 and Form 2 variables each year.

18. **Data Integrity Pledge:** Each center should ensure that all TBIMS staff with data collection or data management duties, including screening and consenting sign the Data Integrity Pledge annually. Project Directors do not need to sign.
19. **Guidelines Sign-off by Project Directors:** On an annual basis, each center Project Director should submit a signed copy of this SOP to the NDSC, to indicate that these guidelines are being followed within his/her center. All signed guidelines will be archived by the NDSC.

These procedures are being followed in my TBI Model System.

_____ _____

Signature of Project Director Date

_____

Center Name

DQ002 Performance Target Monitoring	
Review Committee: Data	Start Date: 6/17/2011
Attachments: None	Last Revised Date: 6/15/2023
Forms: None	Last Reviewed Date: 6/15/2023

Introduction:

The TBIMS are committed to providing an extensive quantity and quality of longitudinal data. In order to achieve this, the Model Systems agreed to institute performance targets for several data collection activities. Performance targets will be evaluated quarterly using "in year statistics" which will reflect a rolling total covering a window of time from any given quarter extending back through the previous three quarters. The following list identifies targets for the most recent 12 months ("In-Year Statistics") that each center should achieve each quarter as indicated in SOP DQ001.

1. Enrolling 80% of eligible participants in the past year
2. Successfully completed 90% of Form 2's due at year 1 in the past year
3. Successfully completed 90% of Form 2's due at year 2 in the past year
4. Successfully completed 80% of Form 2's due at year 5 in the past year
5. Successfully completed 80% of Form 2's due at year 10 in the past year
6. Successfully completed 80% of Form 2's due at year 15 in the past year
7. Successfully completed 80% of Form 2's due at year 20 in the past year
8. Successfully completed 80% of Form 2's due at all follow-up years combined

Additionally, each year a missing data report is run in which the targets are:

1. Not having any identified Form 1 variable have more than 10% missing
2. Not having any identified Form 2 variable have more than 10% missing

This SOP outlines the procedures that will take place if a center does not meet any target.

Purpose:

To standardize the performance target monitoring process and to establish procedures that will assist TBIMS centers in meeting performance targets and to improve center compliance.

Scope:

Performance targets related to the TBIMS National Database quarterly reports.

Responsibilities:

TBIMS center staff is responsible for meeting performance targets and NIDILRR Project Officers and the NDSC staff provide support to achieve compliance as needed.

Procedural steps:

1. The NDSC will send quarterly e-mails with rolling "in year" statistics highlighting performance targets and "best practices" for follow-up to Project Directors/Project Officers notifying them of center performance.
2. If any "in year" performance target is not met for two consecutive quarters, with the assistance of the NDSC, the TBIMS Project Director in consultation with TBIMS Center staff will provide an action plan to their NIDILRR Project Officer within 15 calendar days outlining appropriate steps that will be made in order to ensure targets will be met in subsequent quarters.
    a. Each action plan will be specific to the target that was missed. The NDSC will assist the center by referencing the guidelines and strategies for the recruitment and maximizing follow-up SOP as well as providing solutions that have been used successfully at other centers.
    b. The plan will include a "time to recovery" deadline because some changes a center may make may see immediate results, while others could take up to a year to see the benefits of the change.
3. If a center misses a particular performance target the quarter after the "time to recovery" deadline set forth in the action plan, the Project Director and appropriate center staff will schedule a conference call with their NIDILRR Project Officer and a representative from the NDSC within 15 calendar days to discuss a new action plan with a new time to recovery deadline. For follow-up only centers, the NDSC will also explore options for transferring the cases to the NDSC for conducting follow-up interviews.
4. If best practices are in place further action plans are not required but the TBIMS center must let their NIDILRR Project Officer know if there is a change in implementation of best practices. However, if targets are continually missed an annual re-review will take place. Future NDSC site visits will pay special attention to those best practices.

All NIDILRR grantees are reminded that NIDILRR maintains the right to withhold funding for any grant that fails to make substantial progress toward meeting grant objectives which include enrollment and follow-up for the TBIMS National Database.

Training requirements:

None

Compliance:

All TBIMS centers, longitudinal follow-up centers, NIDILRR and the NDSC will comply with this procedure.

References:

None

History:

Date	Action
6/17/2011	SOP drafted
6/12/2015	Updated NIDRR to NIDILRR
11/22/2016	Added clarifying wording regarding how in year statistics are completed
6/15/2023	Deleted target related to enrolling 100% of the number of participants written into grant in past year. Deleted mention of annual report.

Review Schedule:

At least every 5 years.

DQ003 Prevention and Investigation of Possible Falsification of Data

Review Committee: Data	Effective Date:10/01/2019
Attachments:	Revised Date: 10/01/2019
Forms: OP001 Data Collection Integrity Pledge	Reviewed Date:

Introduction:

Maintaining high level of data quality is a prime objective for all Model Systems but occasionally, a situation may arise that requires investigation of possible fabrication or falsification of data.

Purpose:

To provide strategies to prevent misconduct in data collection and to provide a course of action to be taken when falsification of data is suspected.

Scope:

All current TBIMS centers.

Responsibilities:

All current TBIMS Project Directors and Data Managers.

Strategies to Prevent Misconduct in Data Collection

1. **Staff Recruitment and Hiring (as your Human Resources Department allows):**
   a. Look for gaps in previous employment that might indicate jobs that are not included, and flesh out the history until it's "continuous."
   b. If supervisors in one or more previous positions are not offered as references, inquire whether it would be OK to contact them as well (as your Human Resource Department allows). If the applicant describes problematic behaviors on the part of that supervisor that would make them a "bad reference," offer reassurance that that will be taken into consideration, but that you still need to confirm employment.
   c. Listen to your gut: If a candidate seems "too smooth" or sets off inauthentic radar, don't take that as evidence, but do take it as a reason to probe about issues of honest communication and trust with prior employers.
2. **Training and Reiteration (Data Center and Model System Centers):**
   a. "Provide training on the importance of adhering to and maintaining the integrity of data collection protocols" (Murphy 2016).
   b. Provide a workplace environment that "encourages honesty, discourages falsification, enhances morale, and values data quality (American Statistical Assoc, 2003)

c. Once trained, require data collectors to sign the Data Integrity Pledge to reinforce the importance of high quality, reliable data.

3. **Staff Supervision:**
   a. Hold routine discussions on balancing the desire for productivity with the desire for rigor and accuracy. Don't create a climate where staff feel that they need to meet certain targets "at all costs." Ask data collectors what challenges they are having in meeting targets in an open-ended and collaborative way that emphasizes problem solving. Give positive feedback to staff who come forward with obstacles to enrollment or data collection, or who identify their own mistakes. Routinely give examples of your own challenges and seek input from others, to role model openness in problem solving.
   b. Consider having more than one staff member perform some role in each activity, so that there is always more than one person who knows the mechanics of that function, and so that periodic spot checking of each other's work is facilitated.
   c. Avoid housing staff alone, particularly in areas remote from casual foot traffic "supervision", until their work patterns are clear.
   d. Institute random and unannounced data and file audits, as a matter of routine, so they are not perceived as indicators of suspicion but simply as "good practice" for data completeness and accuracy.
   e. Provide positive feedback from monitoring process with the team.

Procedural Steps for Investigating Possible Falsification of Data:

1. **Assessment:** Determine if data falsification happened. To determine if data falsification happened, and to define the extent of falsification:
   a. Document timeline of suspected behavior
   b. Compile list of records that were potentially affected
   c. Crosscheck resources: date of interview, date of returned mail-out questionnaire, date of data entry, data collector phone logs, any other paper trail
   d. Look for excessive data entry within 1 week of data submission and/or records with large gap between collection date and data entry
2. Notify the NDSC and NIDILRR TBIMS Program Manager and Project Officer within 10 business days of identifying data falsification and provide routine updates of findings and actions taken. At minimum, provide an update within 10 business days from first notifying the NDSC and NIDILRR TBIMS Program Manager and Project Officer. Provide a summary of extent of data manipulation (timeframe, number of forms potentially falsified, number of forms deleted/updated, any personnel action taken, future plan to avoid similar incidence)
3. Rectify data that is potentially corrupted (delete or update). The NDSC will work closely with PI and flag datasets to remove identified records.

Detailed Instructions for Review of Data Sources

Form 1:

1. List cases that may have been affected for dates indicated.

2. Review consent forms
    a. Present
    b. Complete
    c. Witness signatures are present when required
    d. Signatures appear to be valid
3. Look for agreement between the following dates (dates happen in correct order e.g. consent date prior to payment date, consent date prior to data entry date;
    a. Informed consent date
    b. Payment date (for those centers that reimburse for consent)
    c. Data entry date
4. Compare signatures on consent forms and payment forms (for those centers that reimburse for consent)
5. If consent form is incomplete or missing, verify eligibility and re-consent eligible participants.
6. If unable to re-consent, delete Form 1 data.
7. Review data for accuracy.

Form 2:

1. Establish cutoff date for review
    a. Consider when pressure to perform may have begun and/or when Tracking Report/Missing Report numbers improved
    b. Include cases with a large gap (greater than 3 weeks) between interview date & entry date
    c. Include cases where excessive data entry occurred within 1 week of data submission
2. Look for agreement between the following dates:
    a. Date of Interview
    b. Phone logs
    c. Contact forms/logs
    d. Payment/reimbursement logs
    e. Any other paper trail (such as telephone company call records)
3. Call participants/significant others who have a Form 2 in question and recent contact (within 3 months) to verify interview and/or payment for interview. Double-check more stable variables, such as address, employment questions, and FIM physical items to compare with the most recent Form 2 data.
    a. If memory of interview – Keep Form 2
    b. If no memory of interview consider deleting Form 2
    c. If unable to follow-up with participant/significant other, consider deleting Form 2

Training requirements:

None

Compliance:

All current TBIMS centers are responsible for adhering to this policy and its procedures. If a center's institution has policies in place that supersede or conflict with this SOP, the center's policy will take precedent.

References:

Murphy, Joe, et al. Interviewer Falsification: Current and best practices for prevention, detection, and mitigation. Statistical Journal of IAOS. 32 (2016) 313-326

History:

Date	Action
10/01/2019	New policy developed

Review Schedule:

At least every 5 years.

DQ004 Resolving Data Collection and Coding Questions	
Review Committee: Data	Start Date: 4/8/2005
Attachments: None	Last Revised Date: 12/12/2008
Forms: None	Last Reviewed Date: 02/11/2020

Introduction:

The TBIMS are committed to a process of systematic and timely resolution of data collection and coding questions. This will be done in order to: (1) provide a consistent data collection and coding methodology; 2) utilize a multidisciplinary approach; 3) allow for input from all stakeholders; and 4) maintain the highest level of data quality in the TBIMS National Database.

Purpose:

To establish procedures for assuring optimal and timely resolution of data collection and coding questions to maintain the highest level of data quality in the TBIMS National Database.

Scope:

Data Collection and/or coding questions related to the TBIMS National Database proposed by TBIMS staff.

Responsibilities:

The Data Collector and/or TBIMS where data collection and coding question has arisen will submit the question to the NDSC and the following procedural steps will be taken.

Procedural steps:

1. All questions about data collection or coding will be submitted to the NDSC, via email, phone, or Data listserv.
2. Local centers will not "hold" cases with pending questions but will code their problematic variables as "Unknown" and keep track of these cases and update them once the questions are resolved.
3. Within 5 business days of receiving a data collection or coding question, the NDSC will either answer the question or provide notification via the appropriate listserv(s) that satisfactory resolution of the question will require further steps.
4. Further steps are required to obtain satisfactory resolution of a question when either:
    a. The NDSC does not have the expertise needed to answer the question, or
    b. Resolving the question involves changes to the syllabus that require TBIMS approval. (See SOP OP002 – Procedure for Implementing Changes to Database)

5. In cases where the NDSC does not have the expertise needed to answer a question:
    a. The question will be forwarded to the Data Committee Chair within 5 business days and the originator of the question will be cc'd as notification of the status of the question.
    b. If within 10 business days the Data Committee is unable to develop an answer to the question, the Chair will immediately forward the question via email to the "Databusters" and the originator of the question will be cc'd as notification of the status of the question. As of 1/2018, the Medical Databusters are: Allen Brown (MN), Kathy Bell (North TX), Alan Weintraub (CO), Flora Hammond (IN), and Nancy Chiaravalloti (NJ-Kessler); the BTACT Databusters are: Kristen Dams-O'Connor (NY-Mt.Sinai), Joe Giacino (MA), Amanda Rabinowitz (PA-Moss), Mark Sherer (TX-TIRR), Melissa Mayes (WA), and Tom Novack (AL).
    c. If within 10 business days the Databusters are unable to develop an answer to the question, they will immediately notify the Data Committee Chair to seek assistance from persons within and/or external to the TBIMS. They will then obtain an answer within 10 business days and notify the NDSC of the answer.
    d. The NDSC will forward the answer to the originator of the question within 5 business days of receiving it from the Data Committee.
    e. Answers requiring revisions to the syllabus will follow SOP 603b – Procedure for Implementing Changes to Database.

Training requirements:

None

Compliance:

All TBIMS centers, longitudinal follow-up centers and the NDSC will comply with this procedure.

References:

None

History:

Date	Action
4/8/2005	Version used to create this SOP
9/16/2008	Transferred to SOP template
12/12/2008	SOP Review Committee Recommended moving sections related to changes to the national database syllabus to SOP 603b – Procedure for Implementing Changes to Database Approved by SOP Review Committee then by Planning Committee and Project Directors

Date	Action
09/08/2014	SOP Reviewed
02/11/2020	SOP Reviewed

Review Schedule:

At least every 5 years.

DS001 Access to the TBIMS National Database	
Review Committee: Research	Effective Date: 10/01/2019
Attachments: None	Revised Date: 6/17/2023
Forms: DSF101 - Internal Use TBIMS National Database Notification Form; DS002 – TBIMS Project Director Request for National Database Form and DUA; DSF201 - External TBIMS Data Request Form; DSF301 - Public Use Request and Terms of Use Form	Reviewed Date: 1/15/2020

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 (NDB) 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 NDB.

Purpose:

To define the process by which the scientific community and the general public can gain access to the TBIMS NDB.

Scope:

1) All staff, students, and other related personnel involved in the NIDILRR-funded TBIMS Centers who wish to use data from the TBIMS NDB;
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 DS004 *Policy and Procedure for Collaborative Relationships between TBIMS and Non-TBIMS Entities;*
4) All staff, students, and other related personnel at an institution that has a NIDILRR-funded TBIMS Center or Follow-up Center, but not involved in the TBIMS Center or Follow-up Center at that institution who wish to use data from the TBIMS NDB; 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.

Procedural steps:

Procedure for Internal Requests:

This section addresses the use of the TBIMS NDB by TBIMS users (defined as #1, #2 and #3 under Scope above).

Policy

The TBIMS are committed to encouraging the productive and scientifically responsible use of the TBIMS NDB in a timely and effective manner to answer appropriate research questions. The policy includes the following requirements:

1) An analysis may be proposed through the Notification listserv by 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 TBIMS NDB. 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. While a major purpose of the Notification listserv is to ensure that others within and outside the TBIMS are not allowed to propose or perform analyses that are considered largely overlapping, this cannot be assured since the TBIMS Public Use Dataset and TBIMS data stored in the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system can be accessed without using the Notification listserv, although users are encouraged to do so.
5) Anyone receiving the NDB data will need to complete a data use agreement. Internal collaborators, whether PI or other internal researcher, who receive NDB data must abide

by the terms of DSF101 - Internal Use TBIMS National Database Notification Form and DUA and/or DS002 - TBIMS Project Director Request for National Database. Any external collaborator listed on the notification who receives the NDB data must sign DSF201 - External Data Request Form and DUA.

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 and signed DSF101 - Internal Use TBIMS NDB Notification Form and DUA.
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. This should occur 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.** This policy encourages collaboration, while acknowledging projects must be manageable. While every TBIMS investigator has a stake in using the TBIMS NDB they have helped collect and likely has value to contribute to a specific project, there are limited opportunities on a manuscript for substantial contribution to conception, design, analysis, interpretation, and writing. Anyone volunteering to collaborate should critically consider her/his potential contributions and intent to follow through. People offering collaboration should provide very *specific* information about the additional expertise they offer and the roles they are willing to serve on the project. The PI can facilitate this process by specifying gaps that may remain in the study team (e.g., expertise or specific roles). **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, and for each researcher involved being able to contribute in such a way and extent that per the existing guidelines, he/she is entitled to authorship. PIs are encouraged to review the TBIMS authorship policy (SOP OP006 Branding and Authorship Policy) at the time of notification, early in the project development, and again at the time of manuscript preparation to encourage adherence and create opportunities, and to renegotiate authorship as needed.
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 three 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 an existing project that was properly announced through the notification process.
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 NDSC will maintain a list of projects submitted through the notification process and will make it available on the members' side of the NDSC website 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 need to 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 is affiliated with a funded TBIMS center, the center PD will be carbon copied on this correspondence to provide additional visibility and opportunity to solicit an update. If the notification PI does not supply an update within 14 days of receiving the reminder, NDSC will refer the matter to the Research Committee. The Research Committee will review nonresponsive notifications at least twice annually. 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 TBIMS Project Directors' meeting. The Research Committee will review a list of expired and nonresponsive notifications at its meeting, and make decisions in accordance with this SOP to address non-reporting and/or notification expiration.
4) Three years after the date of data receipt of the initial updated notification, the privileges afforded by the notification system and Data Use Agreement automatically expire. Data will not be further analyzed and new results will not be shared/presented/submitted for publication under an expired notification. The original proposer has the option to submit 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. Upon consideration of this explanation, the Research Committee may grant a one-year extension of the approved three-year term. If the extension is not granted, the original proposer must submit a new notification in order to continue work on the project.

Duplicate Studies

1) If a project posted to the notification listserv bears substantial resemblance to one which was previously posted, the PI of the earlier project must notify the PI who has just posted

the new project which is perceived to be duplicative. 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 email to the originating author within 10 working days of the notification, together with a rationale and constructive suggestions for resolving duplication or partial overlap. 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, unless their analysis is based on FITBIR or similar data available to the scientific community at large.

Studies Originating in TBIMS Committees:

1) All research studies utilizing the TBIMS NDB 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 NDB which are proposed in new TBIMS Centers' grant applications submitted to NIDILRR 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 NDB 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 NDB by external TBIMS users (defined as #4 and #5 under Scope above).

The TBIMS Centers have made a substantial long-term contribution in establishing and maintaining the TBIMS NDB. NIDILRR and the TBIMS Centers strongly encourage appropriate collaborative relationships between outside investigators and the TBIMS investigators, and they require proper acknowledgement of the contributions of the TBIMS investigators, even if none join outside investigators on an analysis project.

It has been the expectation of both NIDILRR and the TBIMS Centers that the de-identified TBIMS NDB be made available to the general scientific community. To request the appropriate data, the requestor (i.e., the PI) must send an email to *tbimsdata@craighospital.org* together with a completed 602df – External TBIMS Data Request Form and DUA. The request form will contain information on the affiliation of the PI, her/his collaborators, and the research's 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 will be guided by two factors: feasibility of the proposed analysis, specifically whether the requested TBIMS NDB variables and the available data are appropriate and adequate to address the proposed research question(s); and the scientific overlap of the proposed research question(s) with existing approved proposals, both "internal" and "external." 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 DSF201 – External TBIMS Data Request Form and DUA. These are available for download at *www.tbindsc.org* on the Researchers page. These forms, once complete, can be emailed to *tbimsdata@craighospital.org*.

1) The External TBIMS Data Request Form and the External Data Use Agreement will be reviewed by the NDSC and the TBIMS Research Committee. The foci of the review are twofold: feasibility of the proposed analysis, specifically whether the requested TBIMS NDB variables and the available data are appropriate and adequate to address the proposed research question(s); and the scientific overlap with existing approved proposals, both "internal" and "external."

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 proposal can move forward unless input from the NDSC, Research Committee, and/or Project Directors informs the Notification Lead of any concerns.
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 Centers, 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;** after such time a new External Use Request and Data Use Agreement Form must be sent to the TBIMS NDSC for re-approval. Data will not be further analyzed, and new results will not be shared/presented/submitted for publication under an expired notification.
8) During the term of the project, applicants are to send annual updates to the NDSC, including the name of the PI, title of the project, progress on the project, any presentations/publication or other dissemination that has taken place, 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 Form and TBIMS External Data 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 NDB.
2) Any dissemination of the study findings including all manuscripts, posters, presentations, epubs, digital presentations, and other products must include the following citation for the TBIMS NDB:
    a. Title: Traumatic Brain Injury Model Systems National Database
    b. Author: Traumatic Brain Injury Model Systems Program
    c. Distributor: Traumatic Brain Injury Model Systems National Data and Statistical Center
    d. Persistent identifier: DOI 10.17605/OSF.IO/A4XZB
    e. Date: ____ [insert year of dataset release]
    f. url: http://www.tbindsc.org
    g. Version: https://osf.io/a4xzb/

3) Any dissemination of the study findings including all manuscripts, posters, presentations, epubs, digital presentations, and other products must include the following acknowledgement:

   "This (insert type of publication; e.g., book, report, film) used the Traumatic Brain Injury Model Systems National Database, which is supported by funding from the National Institute on Disability, Independent Living, and Rehabilitation Research. NIDILRR is a Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of this (insert type of publication; e.g., book, report, film) do not necessarily represent the policy of NIDILRR, ACL, or HHS, and you should not assume endorsement by the Federal Government."

4) The PI will apprise the NDSC 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 TBIMS NDB to the NDSC when available.

Unusual Situations

It is expected that users of the TBIMS National Database will follow this policy and procedure and the applicable Data Use Agreement or Terms of Use Agreement.

1) *Failure to Follow the Data Use Agreement.* If users inadvertently violate the User Agreement, corrective action must be taken as soon as the 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 NDB.
2) *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 Procedures for External Requests:

There are two other mechanisms for those external to the TBIMS to access the TBIMS NDB.

The TBIMS NDB is available through the FITBIR informatics system. FITBIR was developed to share data across the entire TBI research field. Sharing data, methodologies, and associated tools, rather than just the 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. See the FITBIR website (https://intbir.nih.gov/fitbir) for complete information on FITBIR's purpose and methodology, including access requirements.

TBIMS data submitted to FITBIR is fully de-identified. The TBIMS data submitted to FITBIR contains the Global Unique Identifier (GUID) and uses the methodology to create the GUID recommended by FITBIR. If it was not possible to assign a GUID to TBIMS cases, a Pseudo-GUID was assigned. The TBIMS data submitted to FITBIR has all variables converted to the

TBI Common Data Elements (CDEs), to the extent possible; otherwise TBIMS variables that do not map to the TBI CDEs are submitted as Unique Data Elements (UDEs). The TBIMS data submitted to FITBIR has an embargo on the usage of the most recent two years of data. The TBIMS NDB is submitted to FITBIR annually.

Public Use Dataset

It is the expectation of both NIDILRR and the TBIMS Centers that a de-identified TBIMS NDB will be made available to the general public. The differences between the Public Use Database and 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 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 DSF301 - Public Use Request and Terms of Use Form. This is available for download at *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 concern 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:

Date	Action
9/25/2019	Combined 602b Internal, 602d External, and added Public Use Dataset Access to create this document.
1/15/2020	Collaboration bullet #1 updated to include language regarding encouraging collaboration while keeping projects manageable, and note about PIs reviewing SOP 608 at the time of notification.
2/18/2021	Updated policy such that a DUA is required for every internal request. Deleted reference to data use that are contained in the internal data use agreement. Deleted need for NDSC for review external publications prior to journal submission. Added description of TBIMS data in FITBIR. Added clarification of public use.

Date	Action
10/7/2022	Updated policy to include information on external collaborators on internal notifications. Also revised the acknowledgement statement to the latest provided by NIDILRR.
6/16/2023	Updated policy to include information on notification expiration procedures.
6/22/2023	Removed all mention of Archived Module Datasets as a separate SOP was developed.

Review schedule:

At least every 5 years.

DS002 TBIMS Project Director Request for National Database	
Review Committee: Research	Effective Date: 11/22/2008
Attachments: None	Revised Date: 6/16/2023
Forms: DSF002 - Project Director Request for National Database FORM	Reviewed Date: 12/7/2019

Introduction:

The TBIMS National Database is available to currently funded TBIMS Project Directors upon request for internal purposes only (e.g., exploring study/analysis ideas, program evaluation, et cetera). In order to track release of the National Database and protect the use of the database, this procedure and request form were developed.

Purpose:

To establish a procedure for currently funded TBIMS Project Directors to request the multicenter TBIMS National Database for internal use, without having to submit an internal notification and DSF101 - Internal Use TBIMS National Database Notification Form.

Scope:

All TBIMS and TBIMS Follow-up Centers, NDSC.

Responsibilities:

All TBIMS and TBIMS Follow-up Centers, NDSC will abide by this procedure.

Procedural steps:

1. This procedure is for TBIMS Project Directors to request the TBIMS NDB for internal purposes only. For dissemination of any information contained in the multicenter TBIMS NDB beyond the requesting Center TBIMS staff, refer to SOP DS001 - Access to the TBIMS National Database.
2. The TBIMS National Database containing all centers' data is updated on a quarterly basis on the following dates: January 15th, March 31st, June 30th, September 30th.
3. The currently funded TBIMS Project Directors are the only persons who may request a copy of the National Database using this procedure. Project Co-Directors may also request a copy if prior arrangements are made in writing between the Project Director and the NDSC.
4. The Project Director (or Co-Director) may not release the National Database to anyone other than those involved in his/her TBIMS project.
5. The Project Director (or Co-Director) will assume responsibility for the protection of the data and release of the National Database to his/her TBIMS staff.

6. In order to receive a copy of the National Database using this procedure, DSF002 – TBIMS Project Director Request for the National Database Form and Data Use Agreement must be completed and signed by the TBIMS Project Director, and sent via email, to the NDSC at tbimsdata@craighospital.org.
7. The version of the National Database available is that which does not contain Protected Health Information (PHI).
8. If a TBIMS wishes to receive a version of the National Database containing PHI defined as those variables in a limited dataset, those specific variables must be requested on the DSF002 – TBIMS Project Director Request for National Database Form and Data Use Agreement.
9. The NDSC will track requests for the National Database.
10. The National Database will be posted in a secure directory in the members only section of the NDSC website and will require security authentication to the website in order to be downloaded.

Training requirements:

None

Compliance:

All TBIMS requestors of the National Database must comply with this procedure.

References:

None

History:

Date	Action
11/22/2008	Database Request Form Transferred to SOP template
12/12/2008	Approved by SOP Committee, Planning Committee and Project Directors
07/07/2014	Reviewed and approved.
06/12/2015	Updated NIDRR to NIDILRR
12/07/2019	Reviewed and updated to coincide with SOP 602f
2/18/2021	Updated procedure to differentiate from internal notification and include data use agreement as part of the request
6/16/2023	Renamed procedure as TBIMS Project Director Request for National Database and Data Use Agreement and clarified DUA for this specific data request purpose.

Review schedule:

At least every 5 years.

TBIMS Project Director Request for National Database Form and Data Use Agreement

This procedure is for TBIMS Project Directors to request the TBIMS NDB for internal purposes only (e.g., exploring study/analysis ideas, program evaluation, et cetera). For dissemination of any information contained in the multicenter TBIMS NDB beyond the Center TBIMS staff, refer to *SOP DS001 – Access to the TBIMS National Database*. The TBIMS National Database containing all centers' data is updated on a quarterly basis on the following dates: January 15th, March 31st, June 30th, September 30th. The currently funded TBIMS Project Directors are the only persons who may request a copy of the National Database using this procedure and form. Project Co-Directors may also request a copy if prior arrangements are made in writing between the Project Director and the NDSC. The Project Director (or Co-Director) may not release the National Database to anyone other than those involved in his/her TBIMS project. The Project Director (or Co-Director) will assume responsibility for the protection and release of the National Database to his/her TBIMS staff. In order to receive a copy of the National Database using this procedure, this form – DSF002 – TBIMS Project Director Request for the TBIMS National Database Form and Data Use Agreement must be completed and signed by the TBIMS Project Director and sent via email to the NDSC at tbimsdata@craighospital.org. The version of the National Database available for download is that which does not contain Protected Health Information (PHI). If a TBIMS wishes to receive a version of the National Database containing PHI, defined as those variables in a limited dataset, those specific variables must be requested on this form - DSF002 – TBIMS Project Director Request for National Database Form and Data Use Agreement. The NDSC will track requests for the National Database. The National Database will be posted in a secure directory in the members only section of the NDSC website and will require security authentication to the website in order to be downloaded.

Name of Requestor: _____

Name of TBI Model System: _____

Date of Request: _____

Date Needed: _____

Are you requesting any TBIMS NDB archived variables? If so, please list:

__ Yes: _____

__ No

[For a list of archived variables go to tbindsc.org and click on the Data Dictionary tab at left; then click on the Data Dictionary button, which brings up the Data Dictionary Explorer. Under the search function, click *Yes* for include ARCHIVED variables; then click the green search button. Under each domain, subdomain or variable, it will indicate if it has been archived.]

Do you intend to link the TBIMS NDB with any other datasets; for example, with any of the geographic identifier variables listed below?

__ Yes

__ No

If so, please describe the data to be linked to the TBIMS National Database and the linking procedures/techniques to be used:

Do you require any geographic identifier or date variables in the limited dataset? If so, please check those required and include justification of why variable is needed for the purposes of your study:

__ StateCode

__ CountyCode

__ CensusTract

__ CensusBlock

__ Zip Code

- __ ZipInj (zip code at injury)
- __ ZipDis (zip code at discharge)
- __ ZipF (zip code at follow-up)

__ The full date of any date variable (e.g., date of injury, date of birth)

Please indicate which dates: _____

Do you require the Socioeconomic Status variables associated with the CensusTract variable that are separate from Form 1 and Form 2?

__ Yes

__ No

Format for Data (check one): ☐**w/o PHI (de-identified)**

☐**w/ PHI (limited dataset as above)**

(check one): ☐**SPSS** ☐**SAS** ☐**CSV**

Please email to: **TBI Model Systems National Data and Statistical Center**
email: tbimsdata@craighospital.org

TBIMS Project Director Data Use Agreement

This Data Use Agreement (the "Agreement") is effective as of [month, day, year] (the "Agreement Effective Date") until [month, day, year] (the "Agreement Termination Date", which will be three (3) years from data release) by and between the Traumatic Brain Injury Model Systems National Data and Statistical Center at **Craig Hospital** ("Covered Entity") and **[name of TBI Model System]** ("Data User").

In 1987, the US Department of Education, National Institute on Disability and Rehabilitation Research (NIDRR), funded the Traumatic Brain Injury Model Systems (TBIMS) Program. The program is currently funded through the Department of Health and Human Services, National Institute of Disability, Independent Living and Rehabilitation Research (NIDILRR – formerly NIDRR). One of the major components of the TBIMS program is a standardized National Database (NDB) for innovative collection, processing, storage and analyses of data relevant to traumatic brain injury (TBI) treatment and outcomes. The TBIMS NDB contains information on cases treated within any TBIMS center funded since 1987, which are located around the United States. Over the years, variables have been added and deleted from the TBIMS NDB. When a variable is deleted, the data collected for this variable is archived and is available by request.

The TBIMS National Data and Statistical Center (TBINDSC) located at Craig Hospital in Englewood, Colorado, is a central resource for researchers and data collectors within the TBIMS program. The primary purpose of the TBINDSC is to advance rehabilitation by increasing the rigor and efficiency of scientific efforts to longitudinally assess the experience of individuals with TBI. The TBINDSC provides technical assistance, training, and methodological consultation to the TBIMS Centers as they collect and analyze longitudinal data from people with TBI in their communities, and as they conduct research on TBI rehabilitation interventions. The TBINDSC (also funded by NIDILRR) houses and manages the TBIMS NDB. This data use agreement is used to allow release of the TBIMS NDB from the TBINDSC to a currently funded TBIMS Center Project Director.

RECITALS

WHEREAS, the TBIMS National Data and Statistical Center as Covered Entity possesses *Individually Identifiable Health Information* that is protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (as hereinafter defined) and the HIPAA Regulations (as hereinafter defined), and is permitted to use or disclose such information only in accordance with HIPAA and HIPAA Regulations;

WHEREAS, Data User performs certain Activities (as hereinafter defined);

WHEREAS, Covered Entity wishes to disclose a Limited Data Set (as hereinafter defined) to Data User for use by Data User in performance of the Activities (as hereinafter defined);

WHEREAS, Covered Entity wishes to ensure that Data User will appropriately safeguard the Limited Data Set in accordance with HIPAA and the HIPAA Regulations; *and*

WHEREAS, Data User agrees to protect the privacy of the Limited Data Set in accordance with the terms and conditions of this Agreement, HIPAA and the HIPAA Regulations;

NOW THEREFORE, Covered Entity and Data User agree as follows:

1. **Definitions** The parties agree that the following terms, when used in this Agreement, shall have the following meanings, provided that the terms set forth below shall be deemed to be modified to reflect any changes made to such terms from time to time as provided in HIPAA and the HIPAA Regulations.
    a. *Activities* shall mean tasks and actions related to the performance of TBI Model System research projects.
    b. *Covered Entity* means a health plan (as defined by HIPAA and the HIPAA Regulations); a health care clearinghouse (as defined by HIPAA and the HIPAA Regulations); or a health care provider (as defined by HIPAA and the HIPAA Regulations) who transmits any health information in electronic form in connection with a transaction covered by the HIPAA Regulations.
    c. *HIPAA* means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.
    d. *HIPAA Regulations* means the regulations promulgated under HIPAA by the United States Department of Health and Human Services, including, but not limited to, 45 C. F. R. Part 160 and 45 C. F. R. Part 164.
    e. *Individually Identifiable Health Information* means information that is a subset of health information, including demographic information collected from an individual, and;
        i. is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
        ii. relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and
            1) that identifies the individual; or
            2) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.
    f. *Limited Data Set* shall have the same meaning as the term "limited data set" in 45 CFR 164.514(e) of the Privacy Rule. A limited data set is Protected Health Information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: names, postal address information (other than town or city, state, and zip code), telephone numbers, fax numbers, electronic mail addresses, social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers (including license plate numbers), device identifiers and serial numbers, web universal resource locators (URLs), internet protocol (IP) address numbers, biometric identifiers (including finger and voice prints), full face photographic images, and any comparable images.

g. *Privacy Rule* shall mean the Standards for Privacy of Individually Identifiable Information at 45 CFR Part 160 and Part 164, Subparts A and E, as amended from time to time.
h. *Protected Health Information* or *PHI* means Individually Identifiable Health Information, excluding certain education and employment records in accordance with the HIPAA regulations, that is transmitted by electronic media; maintained in any medium described in the definition of the term electronic media in the HIPAA Regulations; or transmitted or maintained in any other form or medium.
i. *Required by Law* shall have the same meaning as the term "required by law" in 45 CFR Sect. 164.501 of the Privacy Rule.

2. **Obligations of Covered Entity**
   a. *Limited Data Set*. Covered Entity agrees to disclose the following Protected Health Information to Data User: The Traumatic Brain Injury Model Systems (TBIMS) National Database (NDB) (*a "Limited Data Set"* as defined herein). Such Limited Data Set shall not contain any identifiers of the individual who is the subject of the Protected Health Information, or of relatives, employers or household members of the individual as listed above in section 1f.
   b. *PHI not allowed in limited datasets that is retained by the TBINDSC*. The TBINDSC does retain PHI not allowed in the limited datasets (e.g., street addresses and latitude/longitude coordinates). These data are not available to any internal (TBIMS) or external Data User. These data are only released by the TBINDSC to vendors under a Business Associates Agreement (BAA) for the sole purpose of converting addresses to latitude/longitude coordinates, census tracts, and other geocode information (e.g., distance to particular facilities).
3. **Obligations of Data User**
   a. *Performance of Activities*. Data User may use and disclose the Data Set received from Covered Entity only in connection with the performance of TBI Model System research activities. Data User shall limit the use or receipt of the Data Set to members of the Traumatic Brain Injury Model Systems research team at **[name of TBI Model System]**.
   b. *Nondisclosure Except as Provided in Agreement*. Data User shall not use or further disclose the Limited Data Set except as permitted or required by this Agreement.
      i. Specifically, there is no authorization of redistribution or sharing of the TBIMS NDB with anyone or any entity for any reason.
      ii. Specifically, use of TBIMS data by Data User is restricted to the purpose stated in the request and only for a period of three (3) years from the date of data receipt. New, renewed or further use of data requires a new request and Data Use Agreement.
   c. *Use or Disclosure as if Covered Entity*. Data User may not use or disclose the Limited Data Set in any manner that would violate the requirements of HIPAA or the HIPAA Regulations if used or disclosed by Covered Entity.
   d. *Linking of Limited Data Set*. Linking of the TBIMS NDB data to any other data is prohibited without the explicit description of the data to be linked and the linking procedures to be used in the request for TBIMS NDB data.

i. Data Users linking other data to the TBIMS NDB data will provide the TBINDSC with information regarding the success of their linking (the description and number of cases linked and the procedures employed). Any change in the variables linked requires a new or modified request.
ii. By signing this Data Use Agreement, Data Users acknowledge the responsibilities associated with linking data to the TBIMS NDB, if applicable.

e. *Identification of Individual*. Data User may not use the Limited Data Set to identify or contact any individual who is the subject of the PHI from which the Limited Data Set was created.
f. *Disclosures Required by Law*. Data User may use and disclose the Limited Data Set as required by law. Data User shall advise Covered Entity, in writing, prior to any such disclosure, so that the Covered Entity shall have the opportunity to object or otherwise respond to such disclosure.
g. *Safeguards*. Data User shall use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided by this Agreement.
i. Specifically, Data Users provided with any PHI allowed in limited datasets (with specific justification), are to maintain strict security of PHI, personally supervise its use, and delete the PHI as soon as possible, and signing this Data Use Agreement acknowledges those responsibilities.
h. *Data User's Agent*. Data User shall not disclose the Limited Data Set to any agent or subcontractor of Data User except with the prior written consent of Covered Entity. Data User shall ensure that any agents, including subcontractors, to whom it provides that Limited Data Set agree in writing to be bound by the same restrictions and conditions that apply to Data User with respect to such Limited Data Set.
i. Anyone receiving the NDB data, including any Data User's Agent will need to complete a data use agreement.
i. *Reporting*. Data User shall notify Covered Entity within 48 hours of Data User becoming aware of any use or disclosure of the Limited Data Set in violation of this Agreement or applicable law.
i. Specifically, Data Users are prohibited from attempting to use the TBIMS NDB data to identify TBIMS participants, and any inadvertent identification is to be reported to the TBINDSC.
j. *Notifications, Presentations and Publications*. Data User shall comply with the following Traumatic Brain Injury Model Systems Standard Operating Procedures as related to data use: *SOP DS002 – TBIMS Project Director Request for National Database; SOP DS001 – Access to the TBIMS National Database.*

4. **Material Breach, Enforcement and Termination**
a. *Term*. This Agreement shall be effective as of the Agreement Effective Date, and shall continue until the Agreement Termination Date or in accordance with the provisions of Section 4.c.
b. *Covered Entity's Rights of Access and Inspection*. From time to time upon reasonable notice, or upon a reasonable determination by Covered Entity that Data User may have breached this Agreement, Data User shall make available for

Covered Entity's review and inspection Data User's internal practices, systems, books and records so that Covered Entity may determine Data User's compliance with its obligations under this Agreement. The fact that Covered Entity inspects, or fails to inspect, or has the right to inspect Data User's systems and procedures does not relieve Data User of its responsibility to comply with this Agreement, nor does Covered Entity's (1) failure to detect or (2) detection of, but failure to notify Data User or require Data User's remediation of, any unsatisfactory practices constitute acceptance of such practice or a waiver of Covered Entity's enforcement or termination rights or waiver of Data User's obligations under this Section 4.b. This Section 4.b. shall survive termination of the Agreement.

c. *Termination*. Covered Entity may terminate this Agreement:
    i. immediately if Data User is named as a defendant in a criminal proceeding for a violation of HIPAA or the HIPAA Regulations;
    ii. immediately if there is a finding or stipulation that the Data User has violated one of the following:
        1) any standard or requirement of HIPAA or the HIPAA Regulations; or
        2) any other security or privacy laws as determined or stipulated in an administrative or civil proceeding in which Data User has been joined; or
        3) pursuant to Sections 4.d.iii. or 5.b. of this Agreement.
d. *Remedies*. If Covered Entity determines that Data User has materially breached or violated a material term of this Agreement, Covered Entity may, at its option, pursue any and all of the following remedies:
    i. exercise any of its rights of access and inspection under Section 4.b. of this Agreement;
    ii. any other reasonable steps that Covered Entity, in its sole discretion, shall deem necessary to cure such breach or end such violation; and/or
    iii. terminate this Agreement immediately.
e. *Knowledge of Non-Compliance*. Any non-compliance by Data User with this Agreement or with HIPAA or the HIPAA Regulations automatically will be considered a material breach or violation of a material term of this Agreement if Data User knew or reasonably should have known of such non-compliance and failed to take reasonable steps immediately to cure the non-compliance.
f. *Reporting to United States Department of Health and Human Services*. If Covered Entity's efforts to cure any material breach or end any material violation are unsuccessful as determined in the sole discretion of Covered Entity, and if termination of this Agreement is not feasible, Covered Entity shall report Data User's material breach or material violation to the Secretary of the United States Department of Health and Human Services. Covered Entity shall advise Data User that Covered Entity has made such a report to the United States Department of Health and Human Services and Data User agrees that it shall not have or make any claim(s) whether at law, in equity, or under this Agreement, against Covered Entity with respect to such reports(s).

g. *Disposition of Records*. Upon termination of this Agreement, Data User may retain the Limited Data Set but may only use and disclose the Limited Data Set for the purposes specified in this Agreement and only in accordance with the terms of this Agreement (unless said termination is due to a HIPAA violation, in which case the Limited Data Set must be returned to Covered Entity or destroyed in accordance with HIPAA regulations). However, Data User must abide by institutional protocols that may require destruction of data after Data Use Agreement expiration. This section shall survive termination of this Agreement.

h. *Injunctions*. Covered Entity and Data User agree that material violations of the provisions of this Agreement may cause irreparable harm to Covered Entity. Accordingly, in addition to any other remedies available to Covered Entity at law, in equity, or under this Agreement, in the event of any material breach or violation of any of the provisions of this Agreement by Data User, or any explicit threat thereof, Covered Entity shall be entitled to an injunction or other decree of specific performance with respect to such violation or explicit threat thereof without the necessity of demonstrating actual damages. The parties' respective rights and obligations under this Section 4.h. shall survive termination of the Agreement.

i. *Indemnification.* Data User shall indemnify, hold harmless and defend Covered Entity from and against any and all claims, losses, liabilities, costs and other expenses to the extent resulting from the negligence, recklessness, or intentional misconduct of Data User, including without limitation, the negligent, reckless or intentional acts or omissions of Data User in connection with the representations, duties and obligations of Data User under this Agreement. Covered Entity shall indemnify, hold harmless and defend Data User from and against any and all claims, losses, liabilities, costs and other expenses to the extent resulting from the negligence, recklessness, or intentional misconduct of Covered Entity, including without limitation, the negligent, reckless or intentional acts or omissions of Covered Entity in connection with the representations, duties and obligations of Covered Entity under this Agreement. The parties' respective rights and obligations under this Section 4.i. shall survive termination of the Agreement.

5. **Miscellaneous Terms**

a. *State Law*. Nothing in this Agreement shall be construed to require Data User to use or disclose the Limited Data Set without a written authorization from the individual who is the subject of the PHI from which the Limited Data Set was created; or written authorization from any other person, where such authorization is required under state law for such use or disclosure.

b. *Amendment*. Covered Entity and Data User agree that amendment of this Agreement may be required to ensure that Covered Entity and Data User comply with changes in state and federal laws and regulations relating to the privacy, security, and confidentiality of PHI or the Limited Data Set. Covered Entity may terminate this Agreement upon 30 days written notice in the event that the Covered Entity and Data User cannot agree upon such an amendment that ensures that Covered Entity and Data User will be in compliance with such laws and

regulations within that timeframe. Whether Covered Entity or Data User agrees upon such an amendment is within the sole discretion of each party hereto.

c. *No Third-Party Beneficiaries*. Nothing expressed or implied in this Agreement is intended or shall be deemed to confer upon any person other than Covered Entity and Data User, and their respective successors and assigns, any rights, obligations, remedies or liabilities.

d. *Ambiguities*. The parties agree that any ambiguity in this Agreement shall be resolved in favor or a meaning that complies and is consistent with applicable law protecting the privacy, security and confidentiality of PHI and the Limited Data Set, including, but not limited to, HIPAA and the HIPAA Regulations.

e. *Primacy*. To the extent that any provisions of this Agreement conflict with the provisions of any other agreement or understanding between the parties, this Agreement shall control with respect to the subject matter of this Agreement.

f. *Surviving Provisions in the Event of Termination.* In the event of termination of this Agreement, only those provisions that have been identified herein to survive termination, and specifically the obligations of Data User under Section 3, shall remain in effect after such termination.

g. *Notices*. All notices, demands, and other communications hereunder, except exchanges of technical information and invoices for services rendered, shall be delivered personally to the party hereto which it is addressed or mailed to such party by registered or certified mail, return receipt requested, with postage hereon fully prepaid at the following addresses, unless otherwise subsequently modified by change of address in writing:

If to Data User:

Data User _____
Name _____
Title _____
Address _____

With a copy to:

Name _____
Title _____
Address _____

If to TBINDSC:

The Project Director, TBINDSC
Craig Hospital
3425 S Clarkson St
Englewood, CO 80113

Any notices, demands, and other communications delivered personally shall be deemed to have been received by addressee at the time and date of its delivery. Any notices, demands, and other communications so mailed shall be deemed to have been received by the addressee seven (7) days after the time and date of its being mailed.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the Agreement Effective Date.

Traumatic Brain Injury Model Systems National Data and Statistical Center At Craig Hospital	**[name of TBI Model System]**
_____	_____
Project Director Traumatic Brain Injury Model Systems National Data and Statistical Center Craig Hospital	**[Name of TBIMS Project Director]** **[Title of TBIMS Project Director]**

DS003 Submission of TBIMS Data to FITBIR	
Review Committee: Research	Start Date: 7/1/2017
Attachments: None	Last Revised Date: 12/7/2019
Forms: None	Last Reviewed Date: 12/7/2019

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 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 NDB.

This document outlines the policies and procedures for submitting the TBIMS NDB 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 TBIMS Centers have made a substantial long-term contribution in establishing and maintaining the NDB. NIDILRR and the TBIMS encourage appropriate use of their data by other researchers. They also strongly encourage appropriate collaborative relationships between outside investigators and the TBIMS investigators and they have developed longstanding procedures for external researchers requesting data directly from the TBIMS (see TBIMS Standard Operating Procedure 602f - Access to the TBIMS National Database). This SOP describes the commitment of the TBIMS to contribute the 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 TBIMS Research Committee, TBIMS 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.

Procedural steps:

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 study data will not be submitted to FITBIR.

De-identification of Data

Data submitted to FITBIR will be fully de-identified. The vast majority of TBIMS data are de-identified before entry into the TBIMS NDB stored at the 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 de-identified 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 TBIMS Center 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 de-identified 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 HIPPA 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 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 602f - Access to the TBIMS National Database, 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 602f - Access to the TBIMS National Database 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.

Training requirements:

None

Compliance:

All TBIMS Centers are responsible for adhering to this policy and its procedures.

References:

DS001 - Access to the TBIMS National Database

History:

Date	Action
10/1/2017	Posted to web site
12/7/2019	Updated reference to new SOP 602f – Access to the TBIMS National Database

Review schedule:

At least every 5 years.

DS004 Non-TBIMS Collaborative Relationships	
Review Committee: Research	Start Date: 5/27/2009
Attachments: None	Last Revised Date: 6/12/2015
Forms: None	Last Reviewed Date: 12/7/2019

Introduction:

With recent discussion of potential collaborative projects between the TBI Model Systems (TBIMSs) and non-TBIMS entities, the TBIMS Project Directors expressed a need to define what would be involved in these different types of collaborative relationships.

Purpose:

To establish a policy and procedure for collaborative relationships between the TBIMS and non-TBIMS entities.

Scope:

All current TBIMS Centers, TBIMS Follow-up Centers, the National Data and Statistical Center (NDSC), and other non-TBIMS entities.

Responsibilities:

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

Definitions:

- TBIMS Centers and the NDSC are those that are currently designated and funded by NIDILRR as such.
- TBIMS Follow-up Centers are former TBIMS Centers that are no longer funded as such, but are funded via contract through the NDSC to continue Form II data collection on participants they have already enrolled in the TBIMS National Database (NDB).
- Non-TBIMS entities are those that do not fit the definitions above. Examples include previously funded TBIMS Centers that are neither current TBIMS Centers nor TBIMS Follow-up Centers. Additional examples include, but are not limited to, public and private agencies, organizations and institutions that have never had an affiliation with the TBIMS Centers Program.

Procedure:

1. Non-TBIMS entities interested in collaboration with NIDILRR's TBIMSs related to data collection should contact the NIDILRR TBIMS Program Manager. If the TBIMS Centers are interested in any type of collaboration with a non-TBIMS entity, they should also contact the NIDILRR TBIMS Program Manager.

2. NIDILRR will determine the purpose of the collaborative relationship and determine if there is an 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 NIDILRR TBIMS Program Manager will notify the TBIMS Project Directors via the Directors' listserv and solicit/determine points of contacts (POCs) for the specific collaboration with the TBIMSs.
4. A separate SOP will be developed to detail the nature and level of the collaboration, and may include discussion of the following:
    a. access to TBIMS NDB and module data;
    b. access to data collected by the non-TBIMS entity;
    c. access to members-only sections of the TBIMS website; and
    d. participation in meetings and listservs for TBIMS committees, modules, and SIGs;
5. The NIDILRR TBIMS Program Manager and/or TBIMS POCs will provide updates on collaborations at semi-annual Project Directors meetings.

Training requirements:

None

Compliance:

All currently funded TBIMS Centers, TBIMS Follow-up Centers, the NDSC, previously funded TBIMS Centers and other non-TBIMS entities are responsible for adhering to this policy and its procedures.

References:

None

History:

Date	Action
5/27/2009	New Policy approved by Project Directors
12/03/2010	Revised
12/06/2010	Approved by SOP Committee
07/07/2014	Reviewed and approved with minor editorial changes
6/12/2015	Updated NIDRR to NIDILRR
12/7/2019	Reviewed

Review schedule:

At least every 5 years.

DS005 VA PRCs Collaborative Relationships

Review Committee: Research	Start Date: 5/27/2009
Attachments: None	Last Revised Date: 11/17/2016
Forms: None	Last Reviewed Date: 12/8/2016

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.

Procedural steps:

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' listserv 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 listserv and module listservs for modules for which they are collecting data;
4) participate if desired in Standing Committees (i.e., Data, Research, Dissemination and Planning) and their listservs, except as Chairs, and without voting privileges;
5) participate if desired in TBIMS Special Interest Groups (SIGs) listservs, teleconferences and meetings;
6) participate if desired in module study listservs, 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 listserv 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 listserv;
3) participate (except as Chairs) in Standing Committees (Data, Research, Dissemination, Planning), subscribe to those listservs, 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 OP008).

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 listserv;
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 DSF101) 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 OP008. 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:

Date	Action
5/27/2009	New Policy approved by Project Directors
9/13/2010	Revised draft specifically for VA PRCs
11/2/2010	Revised version approved
7/7/2014	Reviewed and minor clarifying changes made
6/12/2015	Updated NIDRR to NIDILRR
11/17/2016	Revised with changes to VA PRC privileges

Review schedule:

At least every 5 years.

DS006 Follow-up Centers Collaborative Relationships	
Review Committee: Research	Start Date: 12/6/2010
Attachments: None	Last Revised Date: 6/16/2023
Forms: None	Last Reviewed Date: 12/7/2019

Introduction:

A practice within the TBIMS Centers Program is to provide funding to former Traumatic Brain Injury Model Systems (TBIMS) Centers to continue Form II data collection on the participants they had previously enrolled in the TBIMS National Database. These centers are referred to as TBIMS Follow-Up Centers. With the creation of this new affiliation within the TBIMS Centers Program, the Project Directors expressed a need to define the collaborative relationship between the TBIMS and the TBIMS Follow-up Centers.

Purpose:

To detail a policy and procedure for the collaborative relationship between the TBIMS and the TBIMS Follow-up Centers.

Scope:

All current TBIMS Centers, TBIMS Follow-up Centers, and the National Data and Statistical Center (NDSC).

Responsibilities:

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

Definitions:

- TBIMS Centers and the NDSC are those that are currently designated and funded by NIDILRR as such.
- TBIMS Follow-up Centers are former TBIMS Centers that are no longer funded as such, but are funded via contract through the NDSC to continue Form II data collection on participants they have already enrolled in the TBIMS National Database (NDB).

Procedure:

1. The NDSC will contract with TBIMS Follow-up Centers to continue to collect Form II data for the TBIMS National Database.
2. Designated staff at the TBIMS Follow-up Centers should:
    a. subscribe to the Data and the Notification listservs;
    b. follow the TBIMS Internal Notification Policy (see Standard Operating Procedures Manual SOP#602b) to initiate or participate in projects analyzing TBIMS National Database;

c. attend the TBIMS Data Collectors Meetings and Quarterly Data Collectors Teleconferences;
d. have full access to the members only sections of the TBIMS NDSC website; and
e. participate if desired in TBIMS Special Interest Groups (SIGs) listservs, teleconferences and in-person meetings via conference line. The positions of chair and co-chair for TBIMS SIGs will be reserved for staff from currently funded TBIMS Centers.

3. TBIMS Follow-up Centers are not allowed to participate in TBIMS Module projects.

If a TBIMS Follow-up Center wishes to expand their level of collaboration with the TBIMS beyond Form II data collection, they will follow the procedure outlined in SOP 604a for non-TBIMS entities.

Training requirements:

None

Compliance:

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

References:

None

History:

Date	Action
12/6/2010	Approved by SOP Committee
6/12/2015	Updated NIDRR to NIDILRR
12/7/2019	Reviewed
6/16/2023	Prohibited TBIMS Follow-up Centers from participating in Modules

Review schedule:

At least every 5 years.

Internal Use TBIMS National Database Form

Note: This form is for use by TBI Model Systems Centers, previously funded TBIMS Centers that are currently funded as TBIMS Longitudinal Follow-Up Centers, and by Non-TBIMS entities that have been designated as formal collaborators per *SOP DS004 – Non-TBIMS Collaborative Relationships*.

Title of project:

Lead investigator's name:

Lead center:

Contact email address of lead investigator:

Collaborators' names (after each name, please include the collaborator's affiliated center or organization in parentheses):

Notification date:

Project start date:

Completion date (actual or projected):

Date last updated:

Study sample:

Primary research hypotheses:

Abstract (100 words or less):

Primary measures:

Are you requesting any TBIMS NDB archived variables? If so, please list:

__ Yes: _____

__ No

[For a list of archived variables go to tbindsc.org and click on the Data Dictionary tab at left; then click on the Data Dictionary button, which brings up the Data Dictionary Explorer. Under the search function, click *Yes* for include ARCHIVED variables; then click the green search button. Under each domain, subdomain or variable, it will indicate if it has been archived.]

Do you intend to link the TBIMS NDB with any other datasets; for example, with any of the geographic identifier variables listed below?

__ Yes

__ No

If so, please describe the data to be linked to the TBIMS National Database and the linking procedures/techniques to be used:

If the data linked to the TBIMS National Database is from a TBIMS Archived Module Dataset or other TBIMS collaborative research project outside of the TBIMS funding mechanism (e.g., TBIMS Collaborative Studies, study used TBIMS NDB population), please indicate if you intend to archive or share this dataset, and if so, with whom it will be shared/archived: _____

Do you require any geographic identifier or date variables in the limited dataset? If so, please check those required and include justification of why variable is needed for the purposes of your study:

__ StateCode

__ CountyCode

__ CensusTract

__ CensusBlock

__ Zip Code

- __ ZipInj (zip code at injury)
- __ ZipDis (zip code at discharge)
- __ ZipF (zip code at follow-up)

__ The full date of any date variable (e.g., date of injury, date of birth)

Please indicate which dates: _____

Do you require the Socioeconomic Status variables associated with the CensusTract variable that are separate from Form 1 and Form 2?

__ Yes

__ No

In what format would you like the data?

__ SAS

__ SPSS

__ CSV

TBIMS Internal Data Use Agreement

This Data Use Agreement (the "Agreement") is effective as of [month, day, year] (the "Agreement Effective Date") until [month, day, year] (the "Agreement Termination Date", which will be three (3) years from data release) by and between the Traumatic Brain Injury Model Systems National Data and Statistical Center at **Craig Hospital** ("Covered Entity") and **[name of TBI Model System]** ("Data User").

In 1987, the US Department of Education, National Institute on Disability and Rehabilitation Research (NIDRR), funded the Traumatic Brain Injury Model Systems (TBIMS) Program. The program is currently funded through the Department of Health and Human Services, National Institute of Disability, Independent Living and Rehabilitation Research (NIDILRR – formerly NIDRR). One of the major components of the TBIMS program is a standardized National Database (NDB) for innovative collection, processing, storage and analyses of data relevant to traumatic brain injury (TBI) treatment and outcomes. The TBIMS NDB contains information on cases treated within any TBIMS center funded since 1987, which are located around the United States. Over the years, variables have been added and deleted from the TBIMS NDB. When a variable is deleted, the data collected for this variable is archived and is available by request.

The TBIMS National Data and Statistical Center (TBINDSC) located at Craig Hospital in Englewood, Colorado, is a central resource for researchers and data collectors within the TBIMS program. The primary purpose of the TBINDSC is to advance rehabilitation by increasing the rigor and efficiency of scientific efforts to longitudinally assess the experience of individuals with TBI. The TBINDSC provides technical assistance, training, and methodological consultation to the TBIMS Centers as they collect and analyze longitudinal data from people with TBI in their communities, and as they conduct research on TBI rehabilitation interventions. The TBINDSC (also funded by NIDILRR) houses and manages the TBIMS NDB. This data use agreement is used to allow release of the TBIMS NDB from the TBINDSC to a currently funded TBIMS Center, a TBIMS Longitudinal Follow-up Center, or a Non-TBIMS entity that has been designated as a formal collaborator with the TBIMS per TBIMS *SOP DS004*.

RECITALS

WHEREAS, the TBIMS National Data and Statistical Center as Covered Entity possesses *Individually Identifiable Health Information* that is protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (as hereinafter defined) and the HIPAA Regulations (as hereinafter defined), and is permitted to use or disclose such information only in accordance with HIPAA and HIPAA Regulations;

WHEREAS, Data User performs certain Activities (as hereinafter defined);

WHEREAS, Covered Entity wishes to disclose a Limited Data Set (as hereinafter defined) to Data User for use by Data User in performance of the Activities (as hereinafter defined);

WHEREAS, Covered Entity wishes to ensure that Data User will appropriately safeguard the Limited Data Set in accordance with HIPAA and the HIPAA Regulations; *and*

WHEREAS, Data User agrees to protect the privacy of the Limited Data Set in accordance with the terms and conditions of this Agreement, HIPAA and the HIPAA Regulations;

NOW THEREFORE, Covered Entity and Data User agree as follows:

1. **Definitions** The parties agree that the following terms, when used in this Agreement, shall have the following meanings, provided that the terms set forth below shall be deemed to be modified to reflect any changes made to such terms from time to time as provided in HIPAA and the HIPAA Regulations.
    a. *Activities* shall mean tasks and actions related to the performance of TBI Model System research projects.
    b. *Covered Entity* means a health plan (as defined by HIPAA and the HIPAA Regulations); a health care clearinghouse (as defined by HIPAA and the HIPAA Regulations); or a health care provider (as defined by HIPAA and the HIPAA Regulations) who transmits any health information in electronic form in connection with a transaction covered by the HIPAA Regulations.
    c. *HIPAA* means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.
    d. *HIPAA Regulations* means the regulations promulgated under HIPAA by the United States Department of Health and Human Services, including, but not limited to, 45 C. F. R. Part 160 and 45 C. F. R. Part 164.
    e. *Individually Identifiable Health Information* means information that is a subset of health information, including demographic information collected from an individual, and;
        i. is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
        ii. relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and
            1) that identifies the individual; or
            2) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.
    f. *Limited Data Set* shall have the same meaning as the term "limited data set" in 45 CFR 164.514(e) of the Privacy Rule. A limited data set is Protected Health Information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: names, postal address information (other than town or city, state, and zip code), telephone numbers, fax numbers, electronic mail addresses, social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers (including license plate numbers), device identifiers and serial numbers, web universal resource locators (URLs), internet protocol (IP) address numbers, biometric

identifiers (including finger and voice prints), full face photographic images, and any comparable images.

g. *Privacy Rule* shall mean the Standards for Privacy of Individually Identifiable Information at 45 CFR Part 160 and Part 164, Subparts A and E, as amended from time to time.

h. *Protected Health Information* or *PHI* means Individually Identifiable Health Information, excluding certain education and employment records in accordance with the HIPAA regulations, that is transmitted by electronic media; maintained in any medium described in the definition of the term electronic media in the HIPAA Regulations; or transmitted or maintained in any other form or medium.

i. *Required by Law* shall have the same meaning as the term "required by law" in 45 CFR Sect. 164.501 of the Privacy Rule.

2. **Obligations of Covered Entity**

a. *Limited Data Set*. Covered Entity agrees to disclose the following Protected Health Information to Data User: The Traumatic Brain Injury Model Systems (TBIMS) National Database (NDB) (*a "Limited Data Set"* as defined herein). Such Limited Data Set shall not contain any identifiers of the individual who is the subject of the Protected Health Information, or of relatives, employers or household members of the individual as listed above in section 1f.

b. *PHI not allowed in limited datasets that is retained by the TBINDSC*. The TBINDSC does retain PHI not allowed in the limited datasets (e.g., street addresses and latitude/longitude coordinates). These data are not available to any internal (TBIMS) or external Data User. These data are only released by the TBINDSC to vendors under a Business Associates Agreement (BAA) for the sole purpose of converting addresses to latitude/longitude coordinates, census tracts, and other geocode information (e.g., distance to particular facilities).

3. **Obligations of Data User**

a. *Performance of Activities*. Data User may use and disclose the Data Set received from Covered Entity only in connection with the performance of TBI Model System research activities. Data User shall limit the use or receipt of the Data Set to members of the Traumatic Brain Injury Model Systems research team at **[name of TBI Model System]**.

b. *Nondisclosure Except as Provided in Agreement*. Data User shall not use or further disclose the Limited Data Set except as permitted or required by this Agreement.

i. Specifically, there is no authorization of redistribution or sharing of the TBIMS NDB with anyone or any entity for any reason.

ii. Specifically, use of TBIMS data by Data User is restricted to the purpose stated in the request and only for a period of three (3) years from the date of data receipt. New, renewed or further use of data requires a new request and Data Use Agreement.

c. *Use or Disclosure as if Covered Entity*. Data User may not use or disclose the Limited Data Set in any manner that would violate the requirements of HIPAA or the HIPAA Regulations if used or disclosed by Covered Entity.

d. *Linking of Limited Data Set*. Linking of the TBIMS NDB data to any other data is prohibited without the explicit description of the data to be linked and the linking procedures to be used in the request for TBIMS NDB data.
    i. Data Users linking other data to the TBIMS NDB data will provide the TBINDSC with information regarding the success of their linking (the description and number of cases linked and the procedures employed). Any change in the variables linked requires a new or modified request.
    ii. By signing this Data Use Agreement, Data Users acknowledge the responsibilities associated with linking data to the TBIMS NDB, if applicable.
e. *Identification of Individual*. Data User may not use the Limited Data Set to identify or contact any individual who is the subject of the PHI from which the Limited Data Set was created.
f. *Disclosures Required by Law*. Data User may use and disclose the Limited Data Set as required by law. Data User shall advise Covered Entity, in writing, prior to any such disclosure, so that the Covered Entity shall have the opportunity to object or otherwise respond to such disclosure.
g. *Safeguards*. Data User shall use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided by this Agreement.
    i. Specifically, Data Users provided with any PHI allowed in limited datasets (with specific justification), are to maintain strict security of PHI, personally supervise its use, and delete the PHI as soon as possible, and signing this Data Use Agreement acknowledges those responsibilities.
h. *Data User's Agent*. Data User shall not disclose the Limited Data Set to any agent or subcontractor of Data User except with the prior written consent of Covered Entity. Data User shall ensure that any agents, including subcontractors, to whom it provides that Limited Data Set agree in writing to be bound by the same restrictions and conditions that apply to Data User with respect to such Limited Data Set.
    i. Anyone receiving the NDB data, including any Data User's Agent will need to complete a data use agreement.
i. *Reporting*. Data User shall notify Covered Entity within 48 hours of Data User becoming aware of any use or disclosure of the Limited Data Set in violation of this Agreement or applicable law.
    i. Specifically, Data Users are prohibited from attempting to use the TBIMS NDB data to identify TBIMS participants, and any inadvertent identification is to be reported to the TBINDSC.
j. *Notifications, Presentations and Publications*. Data User shall comply with the following Traumatic Brain Injury Model Systems Standard Operating Procedures as related to data use: *SOP DS002 – TBIMS Project Director Request for National Database; SOP DS001 – Access to the TBIMS National Database.*

4. Material Breach, Enforcement and Termination

a. *Term*. This Agreement shall be effective as of the Agreement Effective Date, and shall continue until the Agreement Termination Date or in accordance with the provisions of Section 4.c.

b. *Covered Entity's Rights of Access and Inspection*. From time to time upon reasonable notice, or upon a reasonable determination by Covered Entity that Data User may have breached this Agreement, Data User shall make available for Covered Entity's review and inspection Data User's internal practices, systems, books and records so that Covered Entity may determine Data User's compliance with its obligations under this Agreement. The fact that Covered Entity inspects, or fails to inspect, or has the right to inspect Data User's systems and procedures does not relieve Data User of its responsibility to comply with this Agreement, nor does Covered Entity's (1) failure to detect or (2) detection of, but failure to notify Data User or require Data User's remediation of, any unsatisfactory practices constitute acceptance of such practice or a waiver of Covered Entity's enforcement or termination rights or waiver of Data User's obligations under this Section 4.b. This Section 4.b. shall survive termination of the Agreement.

c. *Termination*. Covered Entity may terminate this Agreement:
    i. immediately if Data User is named as a defendant in a criminal proceeding for a violation of HIPAA or the HIPAA Regulations;
    ii. immediately if there is a finding or stipulation that the Data User has violated one of the following:
        1) any standard or requirement of HIPAA or the HIPAA Regulations; or
        2) any other security or privacy laws as determined or stipulated in an administrative or civil proceeding in which Data User has been joined; or
        3) pursuant to Sections 4.d.iii. or 5.b. of this Agreement.

d. *Remedies*. If Covered Entity determines that Data User has materially breached or violated a material term of this Agreement, Covered Entity may, at its option, pursue any and all of the following remedies:
    i. exercise any of its rights of access and inspection under Section 4.b. of this Agreement;
    ii. any other reasonable steps that Covered Entity, in its sole discretion, shall deem necessary to cure such breach or end such violation; and/or
    iii. terminate this Agreement immediately.

e. *Knowledge of Non-Compliance*. Any non-compliance by Data User with this Agreement or with HIPAA or the HIPAA Regulations automatically will be considered a material breach or violation of a material term of this Agreement if Data User knew or reasonably should have known of such non-compliance and failed to take reasonable steps immediately to cure the non-compliance.

f. *Reporting to United States Department of Health and Human Services*. If Covered Entity's efforts to cure any material breach or end any material violation are unsuccessful as determined in the sole discretion of Covered Entity, and if termination of this Agreement is not feasible, Covered Entity shall report Data User's material breach or material violation to the Secretary of the United States Department of Health and Human Services. Covered Entity shall advise Data User that Covered Entity has made such a report to the United States Department of Health and Human Services and Data User agrees that it shall not have or make

any claim(s) whether at law, in equity, or under this Agreement, against Covered Entity with respect to such reports(s).

g. *Disposition of Records*. Upon termination of this Agreement, Data User may retain the Limited Data Set but may only use and disclose the Limited Data Set for the purposes specified in this Agreement and only in accordance with the terms of this Agreement (unless said termination is due to a HIPAA violation, in which case the Limited Data Set must be returned to Covered Entity or destroyed in accordance with HIPAA regulations). However, Data User must abide by institutional protocols that may require destruction of data after Data Use Agreement expiration. This section shall survive termination of this Agreement.

h. *Injunctions*. Covered Entity and Data User agree that material violations of the provisions of this Agreement may cause irreparable harm to Covered Entity. Accordingly, in addition to any other remedies available to Covered Entity at law, in equity, or under this Agreement, in the event of any material breach or violation of any of the provisions of this Agreement by Data User, or any explicit threat thereof, Covered Entity shall be entitled to an injunction or other decree of specific performance with respect to such violation or explicit threat thereof without the necessity of demonstrating actual damages. The parties' respective rights and obligations under this Section 4.h. shall survive termination of the Agreement.

i. *Indemnification.* Data User shall indemnify, hold harmless and defend Covered Entity from and against any and all claims, losses, liabilities, costs and other expenses to the extent resulting from the negligence, recklessness, or intentional misconduct of Data User, including without limitation, the negligent, reckless or intentional acts or omissions of Data User in connection with the representations, duties and obligations of Data User under this Agreement. Covered Entity shall indemnify, hold harmless and defend Data User from and against any and all claims, losses, liabilities, costs and other expenses to the extent resulting from the negligence, recklessness, or intentional misconduct of Covered Entity, including without limitation, the negligent, reckless or intentional acts or omissions of Covered Entity in connection with the representations, duties and obligations of Covered Entity under this Agreement. The parties' respective rights and obligations under this Section 4.i. shall survive termination of the Agreement.

5. **Miscellaneous Terms**

a. *State Law*. Nothing in this Agreement shall be construed to require Data User to use or disclose the Limited Data Set without a written authorization from the individual who is the subject of the PHI from which the Limited Data Set was created; or written authorization from any other person, where such authorization is required under state law for such use or disclosure.

b. *Amendment*. Covered Entity and Data User agree that amendment of this Agreement may be required to ensure that Covered Entity and Data User comply with changes in state and federal laws and regulations relating to the privacy, security, and confidentiality of PHI or the Limited Data Set. Covered Entity may terminate this Agreement upon 30 days written notice in the event that the Covered Entity and Data User cannot agree upon such an amendment that ensures

that Covered Entity and Data User will be in compliance with such laws and regulations within that timeframe. Whether Covered Entity or Data User agrees upon such an amendment is within the sole discretion of each party hereto.

c. *No Third-Party Beneficiaries*. Nothing expressed or implied in this Agreement is intended or shall be deemed to confer upon any person other than Covered Entity and Data User, and their respective successors and assigns, any rights, obligations, remedies or liabilities.

d. *Ambiguities*. The parties agree that any ambiguity in this Agreement shall be resolved in favor or a meaning that complies and is consistent with applicable law protecting the privacy, security and confidentiality of PHI and the Limited Data Set, including, but not limited to, HIPAA and the HIPAA Regulations.

e. *Primacy*. To the extent that any provisions of this Agreement conflict with the provisions of any other agreement or understanding between the parties, this Agreement shall control with respect to the subject matter of this Agreement.

f. *Surviving Provisions in the Event of Termination.* In the event of termination of this Agreement, only those provisions that have been identified herein to survive termination, and specifically the obligations of Data User under Section 3, shall remain in effect after such termination.

g. *Notices*. All notices, demands, and other communications hereunder, except exchanges of technical information and invoices for services rendered, shall be delivered personally to the party hereto which it is addressed or mailed to such party by registered or certified mail, return receipt requested, with postage hereon fully prepaid at the following addresses, unless otherwise subsequently modified by change of address in writing:

If to Data User:

Data User _____
Name _____
Title _____
Address _____

With a copy to:

Name _____
Title _____
Address _____

If to TBINDSC:

The Project Director, TBINDSC
Craig Hospital
3425 S Clarkson St
Englewood, CO 80113

Any notices, demands, and other communications delivered personally shall be deemed to have been received by addressee at the time and date of its delivery. Any notices, demands, and other communications so mailed shall be deemed to have been received by the addressee seven (7) days after the time and date of its being mailed.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the Agreement Effective Date.

Traumatic Brain Injury Model Systems National Data and Statistical Center At Craig Hospital	**[name of TBI Model System]**
_____	_____
Project Director Traumatic Brain Injury Model Systems National Data and Statistical Center Craig Hospital	**[Name of Authorized Representative]** **[Title of Authorized Representative]**

TBI Model Systems National Database
External Use Request and Data Use Agreement Form

Note: This form is for requesting use of the national database by the general scientific community.

Purpose of use (check all that apply):

__ Research

__ Other (specify): _____

Principal investigator's name:

Principal investigator's position:

Principal investigator's institution(s) (check one):

__Non-profit organization

__For-profit organization

__Government agency

__ Other (specify): _____

Principal investigator's address:

Principal investigator's e-mail:

Collaborators' names (after each name, please include the collaborator's affiliated center(s) or organization(s) in parentheses):

Today's date:

Project start date:

Projected completion date:

Date request last updated:

Proposed Research:

Below please give a brief summary (no more than 4 pages) of the proposed work to be completed with these data. Please follow the format indicated below.

Title of project:

Key words:

Background/Introduction:

Study aim(s):

Research hypotheses:

Methods:

Study sample:

Primary outcome measures:

Secondary outcome measures:

Covariates/confounding measures:

Data analysis plan:

Sample size calculation:

Are you requesting any TBIMS NDB archived variables? If so, please list:

__ Yes: _____

__ No

[For a list of archived variables go to tbindsc.org and click on the Data Dictionary tab at left; then click on the Data Dictionary button, which brings up the Data Dictionary Explorer. Under the search function, click *Yes* for include ARCHIVED variables; then click the green search button. Under each domain, subdomain or variable, it will indicate if it has been archived.]

Do you intend to link the TBIMS NDB with any other datasets; for example, with any of the geographic identifier variables listed below?

__ Yes

__ No

If so, please describe the data to be linked to the TBIMS National Database and the linking procedures/techniques to be used:

With this request, you will receive a de-identified dataset. However, if you require any variables in the limited dataset for the specific purpose of your study, you must indicate below the variables required and the justification of why the variables are needed for the purposes of your study:

__ StateCode

__ CountyCode

__ CensusTract

__ CensusBlock

__ Zip Code

- __ ZipInj (zip code at injury)
- __ ZipDis (zip code at discharge)
- __ ZipF (zip code at follow-up)

__ The full date of any date variable (e.g., date of injury, date of birth)

Please indicate which dates: _____

IRB approval numbers and expiration dates (not necessary for initial submission, but required prior to release of the data):

Dissemination Plan:

__ Publication

__ Presentation

__ Other (specify): _____

In what format would you like the data?

__ SAS

__ SPSS

__ CSV

TBIMS External Data Use Agreement

This Data Use Agreement (the "Agreement") is effective as of [month, day, year] (the "Agreement Effective Date") until [month, day, year] (the "Agreement Termination Date", which will be three (3) years from data release) by and between the Traumatic Brain Injury Model Systems National Data and Statistical Center at **Craig Hospital** ("Covered Entity") and **[name of Data User]** ("Data User").

In 1987, the US Department of Education, National Institute on Disability and Rehabilitation Research (NIDRR), funded the Traumatic Brain Injury Model Systems (TBIMS) Program. The program is currently funded through the Department of Health and Human Services, National Institute of Disability, Independent Living and Rehabilitation Research (NIDILRR – formerly NIDRR). One of the major components of the TBIMS program is a standardized National Database (NDB) for innovative collection, processing, storage and analyses of data relevant to traumatic brain injury (TBI) treatment and outcomes. The TBIMS NDB contains information on cases treated within any TBIMS center funded since 1987, which are located around the United States. Over the years, variables have been added and deleted from the TBIMS NDB. When a variable is deleted, the data collected for this variable is archived and is available by request.

The TBIMS National Data and Statistical Center (TBINDSC) located at Craig Hospital in Englewood, Colorado, is a central resource for researchers and data collectors within the TBIMS program. The primary purpose of the TBINDSC is to advance medical rehabilitation by increasing the rigor and efficiency of scientific efforts to longitudinally assess the experience of individuals with TBI. The TBINDSC provides technical assistance, training, and methodological consultation to 16 TBIMS centers as they collect and analyze longitudinal data from people with TBI in their communities, and as they conduct research toward evidence-based TBI rehabilitation interventions. The TBINDSC (also funded by NIDILRR) houses and manages the TBIMS NDB. This data use agreement is used to allow release of the TBIMS NDB from the TBINDSC to any of the currently funded TBIMS Centers.

For External Requests for the TBIMS NDB, requestors will receive a de-identified dataset. However, if requestors require any variables in the limited dataset for the specific purpose of their study, they must indicate on *DS201F – External Data Request Form and DUA* the variables required and the justification of why the variables are needed for the purposes of their study. If the requestor is a Data User's Agent, the requestor will receive the data from the PI on the study after the latter has received this signed Data Use Agreement and written consent from the Covered Entity.

RECITALS

WHEREAS, the TBIMS National Data and Statistical Center as Covered Entity possesses *Individually Identifiable Health Information* that is protected under the **Health Insurance Portability** and Accountability Act of 1996 (HIPAA) (as hereinafter defined) and the HIPAA Regulations (as hereinafter defined), and is permitted to use or disclose such information only in accordance with HIPAA and HIPAA Regulations;

WHEREAS, Data User performs certain Activities (as hereinafter defined);

WHEREAS, Covered Entity wishes to disclose a Limited Data Set (as hereinafter defined) to Data User for use by Data User in performance of the Activities (as hereinafter defined);

WHEREAS, Covered Entity wishes to ensure that Data User will appropriately safeguard the Limited Data Set in accordance with HIPAA and the HIPAA Regulations; *and*

WHEREAS, Data User agrees to protect the privacy of the Limited Data Set in accordance with the terms and conditions of this Agreement, HIPAA and the HIPAA Regulations;

NOW THEREFORE, Covered Entity and Data User agree as follows:

1. **Definitions** The parties agree that the following terms, when used in this Agreement, shall have the following meanings, provided that the terms set forth below shall be deemed to be modified to reflect any changes made to such terms from time to time as provided in HIPAA and the HIPAA Regulations.
    a. *Activities* shall mean tasks and actions related to the performance of TBI Model System research projects.
    b. *Covered Entity* means a health plan (as defined by HIPAA and the HIPAA Regulations); a health care clearinghouse (as defined by HIPAA and the HIPAA Regulations); or a health care provider (as defined by HIPAA and the HIPAA Regulations) who transmits any health information in electronic form in connection with a transaction covered by the HIPAA Regulations.
    c. *HIPAA* means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.
    d. *HIPAA Regulations* means the regulations promulgated under HIPAA by the United States Department of Health and Human Services, including, but not limited to, 45 C. F. R. Part 160 and 45 C. F. R. Part 164.
    e. *Individually Identifiable Health Information* means information that is a subset of health information, including demographic information collected from an individual, and;
        i. is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
        ii. relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and
            1) that identifies the individual; or
            2) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.
    f. *Limited Data Set* shall have the same meaning as the term "limited data set" in 45 CFR 164.514(e) of the Privacy Rule. A limited data set is Protected Health

Information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: names, postal address information (other than town or city, state, and zip code), telephone numbers, fax numbers, electronic mail addresses, social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers (including license plate numbers), device identifiers and serial numbers, web universal resource locators (URLs), internet protocol (IP) address numbers, biometric identifiers (including finger and voice prints), full face photographic images, and any comparable images.

g. *Privacy Rule* shall mean the Standards for Privacy of Individually Identifiable Information at 45 CFR Part 160 and Part 164, Subparts A and E, as amended from time to time.
h. *Protected Health Information* or *PHI* means Individually Identifiable Health Information, excluding certain education and employment records in accordance with the HIPAA regulations, that is transmitted by electronic media; maintained in any medium described in the definition of the term electronic media in the HIPAA Regulations; or transmitted or maintained in any other form or medium.
i. *Required by Law* shall have the same meaning as the term "required by law" in 45 CFR Sect. 164.501 of the Privacy Rule.

2. **Obligations of Covered Entity**
   a. *Limited Data Set*. Covered Entity agrees to disclose the following Protected Health Information to Data User: The Traumatic Brain Injury Model Systems (TBIMS) National Database (NDB) (*a "Limited Data Set"* as defined herein). Such Limited Data Set shall not contain any identifiers of the individual who is the subject of the Protected Health Information, or of relatives, employers or household members of the individual as listed above in section 1f.
   b. *PHI not allowed in limited datasets that is retained by the TBINDSC*. The TBINDSC does retain PHI not allowed in the limited datasets (e.g., street addresses and latitude/longitude coordinates). These data are not available to any internal (TBIMS) or external Data User. These data are only released by the TBINDSC to vendors under a Business Associates Agreement (BAA) for the sole purpose of converting addresses to latitude/longitude coordinates, census tracts, and other geocode information (e.g., distance to particular facilities).
3. **Obligations of Data User**
   a. *Performance of Activities*. Data User may use and disclose the Data Set received from Covered Entity only in connection with the performance of TBI Model System research activities. Data User shall limit the use or receipt of the Data Set to members of the Traumatic Brain Injury Model Systems research team at **[name of institution where research is being conducted]**.
   b. *Nondisclosure Except as Provided in Agreement*. Data User shall not use or further disclose the Limited Data Set except as permitted or required by this Agreement.

i. Specifically, there is no redistribution or sharing of the TBIMS NDB with anyone or any entity for any reason, except that required for journal publication or by research funding agencies. In which case, the Data User must notify the TBINDSC in writing, and any PHI must be removed prior to redistribution/sharing for this purpose.
ii. **Specifically, use of TBIMS data is restricted to the purpose stated in the request and only for a period of two (2) years from the date of data receipt. New or further use of data requires a new request and Data Use Agreement. Data will not be further analyzed and new results will not be shared/presented/submitted for publication under an expired notification.**

c. *Use or Disclosure as if Covered Entity*. Data User may not use or disclose the Limited Data Set in any manner that would violate the requirements of HIPAA or the HIPAA Regulations if used or disclosed by Covered Entity.
d. *Linking of Limited Data Set*. Linking of the TBIMS NDB data to any other data is prohibited without the explicit description of the data to be linked and the linking procedures to be used in the request for TBIMS NDB data.
    i. Data Users linking other data to the TBIMS NDB data will provide the TBINDSC with information regarding the success of their linking (the description and number of cases linked and the procedures employed) and information on how other researchers can request the linked variables.
    ii. If allowed by the source of the data linked to the TBIMS NDB cases, the data linked to TBIMS cases may be redistributed by the original requestor along with the TBIMS NDB variables Mod1Id (a unique case ID assigned by the TBINDSC for Form 1 variables) and Mod2Id (a unique case ID assigned by the TBINDSC for Form 2 variables), but not any other TBIMS NDB data. [This is intended to prohibit the redistribution of the TBIMS NDB data, while still allowing others to re-link the non-TBIMS NDB data to TBIMS NDB data based on the Mod1Id and Mod2Id stored and distributed as a part of the non-TBIMS NDB data.]
    iii. By signing this Data Use Agreement, Data Users acknowledge the responsibilities associated with linking data to the TBIMS NDB, if applicable.
e. *Identification of Individual*. Data User may not use the Limited Data Set to identify or contact any individual who is the subject of the PHI from which the Limited Data Set was created.
f. *Disclosures Required by Law*. Data User may use and disclose the Limited Data Set as required by law. Data User shall advise Covered Entity, in writing, prior to any such disclosure, so that the Covered Entity shall have the opportunity to object or otherwise respond to such disclosure.
g. *Safeguards*. Data User shall use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided by this Agreement.

i. Specifically, Data Users provided with any PHI allowed in limited datasets (with specific justification), are to maintain strict security of PHI, personally supervise its use, and delete the PHI as soon as possible, and signing this Data Use Agreement acknowledges those responsibilities.

h. *Data User's Agent*. Data User shall not disclose the Limited Data Set to any agent or subcontractor of Data User except with the prior written consent of Covered Entity. Data User shall ensure that any agents, including subcontractors, to whom it provides that Limited Data Set agree in writing to be bound by the same restrictions and conditions that apply to Data User with respect to such Limited Data Set.
   i. Anyone receiving the NDB data, including any Data User's Agent will need to complete a data use agreement. Any external collaborator listed on the notification who receives the NDB data must sign *DS201F – External Data Request Form and DUA*.

i. *Reporting*. Data User shall notify Covered Entity within 48 hours of Data User becoming aware of any use or disclosure of the Limited Data Set in violation of this Agreement or applicable law.
   i. Specifically, Data Users are prohibited from attempting to use the TBIMS NDB data to identify TBIMS participants, and any inadvertent identification is to be reported to the TBINDSC.
   ii. **Data Users will provide annual updates to the TBINDSC on the progress of their project, including any dissemination (e.g., digital or hard copy abstracts, presentations, publications, or any other products.)**

j. *Dissemination of Study Findings.*
   i. Data Users will include the following citation for the TBIMS National Database in any dissemination of the study findings including all digital or hard copy manuscripts, posters, presentations, and other products:
      1) Title: Traumatic Brain Injury Model Systems National Database
      2) Author: Traumatic Brain Injury Model Systems Centers Program
      3) Distributor: Traumatic Brain Injury Model Systems National Data and Statistical Center
      4) Persistent identifier: DOI 10.17605/OSF.IO/A4XZB
      5) Date: ____ [insert year of data release]
      6) url: http://www.tbindsc.org
      7) Version: https://osf.io/a4xzb/
   ii. Data Users will include the following acknowledgement in any dissemination of study findings including all digital or hard copy manuscripts, posters, presentations, and other products:

      "This (insert type of publication; e.g., book, report, film) used the Traumatic Brain Injury Model Systems National Database, which is supported by funding from the National Institute on Disability, Independent Living, and Rehabilitation Research. NIDILRR is a

Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of this (insert type of publication; e.g., book, report, film) do not necessarily represent the policy of NIDILRR, ACL, or HHS, and you should not assume endorsement by the Federal Government."

iii. Data Users will provide the TBINDSC the URL and complete citation for any publication (written or electronic) of research using the TBIMS NDB.

4. **Material Breach, Enforcement and Termination**
   a. *Term*. This Agreement shall be effective as of the Agreement Effective Date, and shall continue until the Agreement Termination Date or in accordance with the provisions of Section 4.c.
   b. *Covered Entity's Rights of Access and Inspection*. From time to time upon reasonable notice, or upon a reasonable determination by Covered Entity that Data User may have breached this Agreement, Data User shall make available for Covered Entity's review and inspection Data User's internal practices, systems, books and records so that Covered Entity may determine Data User's compliance with its obligations under this Agreement. The fact that Covered Entity inspects, or fails to inspect, or has the right to inspect Data User's systems and procedures does not relieve Data User of its responsibility to comply with this Agreement, nor does Covered Entity's (1) failure to detect or (2) detection of, but failure to notify Data User or require Data User's remediation of, any unsatisfactory practices constitute acceptance of such practice or a waiver of Covered Entity's enforcement or termination rights or waiver of Data User's obligations under this Section 4.b. This Section 4.b. shall survive termination of the Agreement.
   c. *Termination*. Covered Entity may terminate this Agreement:
      i. immediately if Data User is named as a defendant in a criminal proceeding for a violation of HIPAA or the HIPAA Regulations;
      ii. immediately if there is a finding or stipulation that the Data User has violated one of the following:
         1) any standard or requirement of HIPAA or the HIPAA Regulations; or
         2) any other security or privacy laws as determined or stipulated in an administrative or civil proceeding in which Data User has been joined; or
         3) pursuant to Sections 4.d.iii. or 5.b. of this Agreement.
   d. *Remedies*. If Covered Entity determines that Data User has materially breached or violated a material term of this Agreement, Covered Entity may, at its option, pursue any and all of the following remedies:
      i. exercise any of its rights of access and inspection under Section 4.b. of this Agreement;
      ii. any other reasonable steps that Covered Entity, in its sole discretion, shall deem necessary to cure such breach or end such violation; and/or
      iii. terminate this Agreement immediately.

e. *Knowledge of Non-Compliance*. Any non-compliance by Data User with this Agreement or with HIPAA or the HIPAA Regulations automatically will be considered a material breach or violation of a material term of this Agreement if Data User knew or reasonably should have known of such non-compliance and failed to take reasonable steps immediately to cure the non-compliance.

f. *Reporting to United States Department of Health and Human Services*. If Covered Entity's efforts to cure any material breach or end any material violation are unsuccessful as determined in the sole discretion of Covered Entity, and if termination of this Agreement is not feasible, Covered Entity shall report Data User's material breach or material violation to the Secretary of the United States Department of Health and Human Services. Covered Entity shall advise Data User that Covered Entity has made such a report to the United States Department of Health and Human Services and Data User agrees that it shall not have or make any claim(s) whether at law, in equity, or under this Agreement, against Covered Entity with respect to such reports(s).

g. *Disposition of Records*. Upon termination of this Agreement, Data User may retain the Limited Data Set but may only use and disclose the Limited Data Set for the purposes specified in this Agreement and only in accordance with the terms of this Agreement (unless said termination is due to a HIPAA violation, in which case the Limited Data Set must be returned to Covered Entity or destroyed in accordance with HIPAA regulations). However, Data User must abide by institutional protocols that may require destruction of data after Data Use Agreement expiration. This section shall survive termination of this Agreement.

h. *Injunctions*. Covered Entity and Data User agree that material violations of the provisions of this Agreement may cause irreparable harm to Covered Entity. Accordingly, in addition to any other remedies available to Covered Entity at law, in equity, or under this Agreement, in the event of any material breach or violation of any of the provisions of this Agreement by Data User, or any explicit threat thereof, Covered Entity shall be entitled to an injunction or other decree of specific performance with respect to such violation or explicit threat thereof without the necessity of demonstrating actual damages. The parties' respective rights and obligations under this Section 4.h. shall survive termination of the Agreement.

i. *Indemnification.* Data User shall indemnify, hold harmless and defend Covered Entity from and against any and all claims, losses, liabilities, costs and other expenses to the extent resulting from the negligence, recklessness, or intentional misconduct of Data User, including without limitation, the negligent, reckless or intentional acts or omissions of Data User in connection with the representations, duties and obligations of Data User under this Agreement. Covered Entity shall indemnify, hold harmless and defend Data User from and against any and all claims, losses, liabilities, costs and other expenses to the extent resulting from the negligence, recklessness, or intentional misconduct of Covered Entity, including without limitation, the negligent, reckless or intentional acts or omissions of

Covered Entity in connection with the representations, duties and obligations of Covered Entity under this Agreement. The parties' respective rights and obligations under this Section 4.i. shall survive termination of the Agreement.

5. **Miscellaneous Terms**
   a. *State Law*. Nothing in this Agreement shall be construed to require Data User to use or disclose the Limited Data Set without a written authorization from the individual who is the subject of the PHI from which the Limited Data Set was created; or written authorization from any other person, where such authorization is required under state law for such use or disclosure.
   b. *Amendment*. Covered Entity and Data User agree that amendment of this Agreement may be required to ensure that Covered Entity and Data User comply with changes in state and federal laws and regulations relating to the privacy, security, and confidentiality of PHI or the Limited Data Set. Covered Entity may terminate this Agreement upon 30 days written notice in the event that the Covered Entity and Data User cannot agree upon such an amendment that ensures that Covered Entity and Data User will be in compliance with such laws and regulations within that timeframe. Whether Covered Entity or Data User agrees upon such an amendment is within the sole discretion of each party hereto.
   c. *No Third-Party Beneficiaries*. Nothing expressed or implied in this Agreement is intended or shall be deemed to confer upon any person other than Covered Entity and Data User, and their respective successors and assigns, any rights, obligations, remedies or liabilities.
   d. *Ambiguities*. The parties agree that any ambiguity in this Agreement shall be resolved in favor or a meaning that complies and is consistent with applicable law protecting the privacy, security and confidentiality of PHI and the Limited Data Set, including, but not limited to, HIPAA and the HIPAA Regulations.
   e. *Primacy*. To the extent that any provisions of this Agreement conflict with the provisions of any other agreement or understanding between the parties, this Agreement shall control with respect to the subject matter of this Agreement.
   f. *Surviving Provisions in the Event of Termination.* In the event of termination of this Agreement, only those provisions that have been identified herein to survive termination, and specifically the obligations of Data User under Section 3, shall remain in effect after such termination.
   g. *Notices*. All notices, demands, and other communications hereunder, except exchanges of technical information and invoices for services rendered, shall be delivered personally to the party hereto which it is addressed or mailed to such party by registered or certified mail, return receipt requested, with postage hereon fully prepaid at the following addresses, unless otherwise subsequently modified by change of address in writing:

If to Data User:

Data User _____
Name _____
Title _____
Address _____

With a copy to:

Name _____
Title _____
Address _____

If to TBINDSC:

The Project Director, TBINDSC
Craig Hospital
3425 S Clarkson St
Englewood, CO 80113

Any notices, demands, and other communications delivered personally shall be deemed to have been received by addressee at the time and date of its delivery. Any notices, demands, and other communications so mailed shall be deemed to have been received by the addressee seven (7) days after the time and date of its being mailed.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the Agreement Effective Date.

Traumatic Brain Injury Model Systems National Data and Statistical Center At Craig Hospital	**[name of Data User]**
_____	_____
Project Director Traumatic Brain Injury Model Systems National Data and Statistical Center Craig Hospital	**[Name of Data User]** **[Title of Data User]**

TBI Model Systems National Database
Public Use Request and Terms of Use Form

Note: This form is for requesting use of the national database by the general public.

Today's date:

Requestor's first name:

Requestor's last name:

Requestor's email address:

Requestor's institution or organization:

Institution Type:

__Non-profit organization
__Commercial
__Academic
__ Other (specify): _____

Number of years in scientific research:

__ Less than 5
__ 5 - 10
__ 10+

Study Name:

Describe Request:

Terms of Use:

Please read the Terms of Use below. If you agree to them, sign your name at the bottom of the form. These Terms of Use form an agreement between the Traumatic Brain Injury Model Systems National Data and Statistical Center ("NDSC") and the person agreeing to these Terms of Use (the "AUTHORIZED USER" as further defined below).

Definitions

AUTHORIZED USER

The individual who completes, signs and agrees to the Terms of Use for the TBIMS NDB Public Use Database.

NDSC

Traumatic Brain Injury Model Systems National Data and Statistical Center

NIDILRR

National Institute on Disability, Independent Living, and Rehabilitation Research

PROMISE OF CONFIDENTIALITY

A promise to a RESEARCH PARTICIPANT that the information the RESEARCH PARTICIPANT provides will not be disseminated without the permission of the RESEARCH PARTICIPANT; that the fact that the RESEARCH PARTICIPANT participated in the study will not be disclosed; and that disseminated information will include no linkages to the identity of the RESEARCH PARTICIPANT. Such a promise encompasses traditional notions of both confidentiality and anonymity. Names and other identifying information regarding RESEARCH PARTICIPANTS, proxies, or other persons on whom the RESEARCH PARTICIPANT or proxy provides information, are presumed to be confidential.

RESEARCH PARTICIPANT

A person or organization observed for purposes of research. Also called a respondent, case or subject. A RESEARCH PARTICIPANT is generally a survey respondent or informant, experimental or observational subject, focus group participant, or any other person providing information to a study or on whose behalf a proxy provides information.

Terms of Use:

The NDSC hosts the TBI Model Systems National Database ("TBIMS NDB"). The NDSC adheres to the principles that require the data consumer to comply with access regulations imposed both by law and by the data repository, and to conform to codes of conduct that are generally accepted in higher education and scientific research for the exchange of knowledge and information.

The NDSC will distribute the TBIMS NDB pursuant to these Terms of Use. By signing this document, you signify your agreement to comply with the Terms of Use stated below.

Use of TBIMS data is restricted to the purpose stated in the request and only for a period of two (2) years from the date of data receipt. New or further use of data requires a new request and signed Terms of Use.

Privacy of RESEARCH PARTICIPANTS

The TBIMS NDB to which you will be given access if you agree to these Terms of Use is de-identified data within the meaning of the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations. (*See* 45 CFR 164.514). Any intentional re-identification of a RESEARCH PARTICIPANT or unauthorized disclosure of his or her confidential information violates the PROMISE OF CONFIDENTIALITY given to the RESEARCH PARTICIPANTS. Therefore, AUTHORIZED USERS agree:

- To use the TBIMS NDB solely for research or statistical purposes and not for investigation of specific RESEARCH PARTICIPANTS
- To make no efforts to re-identify a RESEARCH PARTICIPANT
- TO MAKE no use of the identity of any RESEARCH PARTICIPANT discovered inadvertently, and to advise the NDSC of any such discovery (tbimsdata@craighospital.org).

Redistribution of Data

You agree that you may only share the TBIMS NDB with other AUTHORIZED USERS. Each and every person you intend to share the TBIMS NDB with must complete, sign and submit to the NDSC a duplicate version of this form, and agree to these Terms of Use to become an AUTHORIZED USER. If the intended recipient of the TBIMS NDB data does not submit a duplicate request and agree to these Terms of Use, you may not share the TBIMS NDB with him/her. Your sharing the TBIMS NDB with a person who is not an AUTHORIZED USER is a violation of these Terms of Use. In the event that a person who is not an AUTHORIZED USER obtains the TBIMS NDB, you agree that you will promptly notify the NDSC of the data accessed and the person who received it.

Thus, there is no redistribution or sharing of the TBIMS NDB with anyone or any entity for any reason, except that required for journal publication or by research funding agencies. Journal editors or grant makers may, in certain circumstances, request a copy of the data on which a paper or report is based; in which case, the AUTHORIZED USER must notify the NDSC in writing prior to redistribution/sharing for this purpose.

You further agree not to redistribute the TBIMS NDB unless:

- You are assisting AUTHORIZED USERS with obtaining data, or
- You are collaborating with other AUTHORIZED USERS to analyze the data for research or instructional purposes.

When sharing the TBIMS NDB in these approved ways, you must include all accompanying files with the TBIMS NDB data, including these Terms of Use.

Citing Data

You agree to reference the recommended bibliographic citation* in any publication (epub, digital or hard copy) that employs resources provided by the NDSC.

Authors of publications based on the TBIMS NDB are required to send citations of their published works to the NDSC for inclusion in a database of related publications (tbimsdata@craighospital.org).

*Each citation must include the basic elements that allow a unique dataset to be identified over time:

- 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
- URL: http://www.tbindsc.org
- Date: ____ [insert the year of data release]
- Version: https://osf.io/a4xzb/

Acknowledgement:

Any dissemination of the study findings including all manuscripts, posters, presentations, epubs, and other digital or hard copy products must include the following acknowledgement:

> "This (insert type of publication; e.g., book, report, film) used the Traumatic Brain Injury Model Systems National Database, which is supported by funding from the National Institute on Disability, Independent Living, and Rehabilitation Research. NIDILRR is a Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of this (insert type of publication; e.g., book, report, film) do not necessarily represent the policy of NIDILRR, ACL, or HHS, and you should not assume endorsement by the Federal Government."

Disclaimer

You acknowledge that the original collector of the TBIMS NDB data, the NDSC and NIDILRR bear no responsibility for your use of the TBIMS NDB data or for interpretations or inferences based upon such uses.

Violations

If the NDSC determines that you have violated these Terms of Use, it can and will impose sanctions. The sanctions it could choose to impose include without limitation:

- NDSC may revoke these Terms of Use, demand the return of the data in question, and deny all future access to TBIMS NDB data.
- The violation may be reported to the Research Integrity Officer, Institutional Review Board, or Human Subjects Review Committee of the AUTHORIZED USER's institution. A range of sanctions are available to institutions, including revocation of tenure and termination.
- If the confidentiality of human subjects has been violated, the case may be reported to the Federal Office for Human Research Protections. This may result in an investigation of the AUTHORIZED USER's institution, which can further result in institution-wide sanctions, including the suspension of all research grants.
- A court may award the payment of damages to any individual(s)/organization(s) harmed by the breach of these Terms of Use.

I agree to abide by and be bound by these Terms of Use.

_____ _____

Printed Name Date

_____

Signature

(Please sign your name to indicate your intent to be bound by these Terms of Use.)

NDSC
National Data and Statistical Center
Traumatic Brain Injury Model System

TBIMS Data Collection Integrity Pledge

According the NIH, **research integrity** is defined as the use of honest and verifiable methods in proposing, performing and evaluating research. Data collectors play a vital role within the scientific research process because data collection activities are a crucial step toward valid and verifiable research analysis.

This pledge is a statement of my personal commitment to achieving integrity and honesty.

As part of the Model Systems research data collection team, I am responsible for holding myself to high scientific research values. I pledge to be honest, accurate, efficient, respectful and objective:

- ☐ I will convey information truthfully.
- ☐ I will report data accurately and precisely.
  - I will not fabricate or falsify data;
  - I will avoid independently interpreting participant's responses while coding;
  - I will seek verification of data when appropriate.
- ☐ I will make every attempt to follow best practices and Model System procedures and policies.
- ☐ I will honor and respect our participants and teammates.

Name: _____

Signature: _____ Date: _____

Data fabrication is a rare but serious breach of data integrity. Falsification of data includes the intentional departure from Model System procedures, unreported by the interviewer, which could result in the contamination of data (deliberately misreporting codes or falsifying procedures; intentionally misrepresenting data collection procedures to management; and miscoding an answer to a question in order to avoid follow-up questions). Fabrication of data is reporting data that are not provided by the designated respondent as answers of that respondent.

NIDILRR
National Institute on Disability, Independent Living, and Rehabilitation Research

OP002 Implementing Changes to the National Database	
Review Committee: Planning	Start Date: 9/8/1999
Attachments: OP003 Timeline for Implementing Changes to the National Database (addendum)	Last Revised Date: 9/18/2023
Forms: OPF002 – Implementing Changes to the Database Form	Last Reviewed Date: 9/18/2023

Introduction:

The TBIMS has established criteria for implementing changes to the TBIMS National Database (NDB).

Purpose:

To institute a standardized policy for implementing changes to the NDB.

Scope:

All current TBIMS centers and the NDSC.

Responsibilities:

All current TBIMS and NDSC staff who wish to implement changes to the NDB.

Definitions:

Variable – a single coded variable (e.g., for example, EduYears – Years of Education). **Variable groups** – a group of variables on a common topic, or an instrument with multiple items, with all variables within the group coded individually with similar or different coding schemes (e.g., Employment Status is a variable group containing 2 variables, Emp1 – Employment Status: Primary and Emp2 – Employment Status: Secondary. GOSE – Glasgow Outcome Scale – Extended is a variable group containing 21 variables, GOSCommands – Obey Simple Commands/Say Words, GOSAssistAll – Assistance is Essential at Home, etc.). **Codes** – each variable has a number of codes with corresponding definitions (e.g., the variable DrugsF – Drug Use has 5 codes 0 = No, 1 = Yes, 66 = Variable DNE, 77 = Refused, 88 = Not Applicable, 99 = Unknown).

Procedural steps:

The NDSC must obtain TBIMS approval, as described below, before implementing any changes to the TBIMS National Database. The following describes the levels of data dictionary revisions and the corresponding procedure.

1. **Level I data dictionary revisions** are changes that require (a) clarifying of one or more points in an existing data dictionary page and/or (b) adding one or more new or improved examples. These types of revisions do not involve adding or deleting any variable groups,

variables or codes, regardless if they involve additional data collection from a participant (e.g., method of interview data collection). They can involve clarifying definitions, adding or deleting items included in a code (e.g., adding or deleting items included in code 4 correctional institution, such as a half-way house, for the variable residence at injury).

a. If a Level I data dictionary revision is required, within 10 business days of learning that a Level I revision is required, the NDSC will prepare a draft revision of the data dictionary page(s) that have changes and send it to the Data Committee for comment and approval.

b. Within 10 business days, the Data Committee will respond with approval or further revision/clarification as appropriate in order to arrive at a final version of the revision.

c. Within 30 days of the beginning of the next data collection quarter, the NDSC will prepare and post on the website an updated data dictionary page, and will implement the updated data dictionary page on the first day of that quarter.

2. **Level II data dictionary revisions** are changes that require adding or deleting codes from an existing variable, or require deleting variables or variable groups. It does not include adding variable groups or single variables, regardless if they involve additional data collection from a participant.

a. If a Level II data dictionary revision is required, within 10 business days of learning that a Level II revision is required, the NDSC will prepare a draft revision of the data dictionary page(s) that have changes and send it to the Data Committee for comment and approval.

b. If the addition or deletion of variable codes or deletion of variables/variable groups will cause data collected in the future to be incompatible with data already in the database (e.g., two codes are collapsed into the same code or a new code is added; both changes would require recoding), the NDSC will also prepare a recommendation regarding how the incompatibility between old data and new data will be handled.

c. Once the Data Committee has had an opportunity to comment on the proposed revisions, the NDSC will prepare a final version for Data Committee majority vote.

d. Once approved by the Data Committee, the Data Committee chair will recommend approval by the Project Directors by majority vote (1 vote per center) via email or in-person at the Project Directors meeting.

e. Once approved by the Project Directors, the NDSC will prepare and distribute updated data dictionary pages and data collection forms for Centers to obtain IRB approval. The approved changes will go into effect the quarter following the next data submission (e.g., changes approved June 15; next data submission June 30; NDSC sends forms to centers July 15 for IRB submission; data submission September 30; changes go into effect October 1).

3. **Level III data dictionary revisions** are changes that require adding variable groups, variables or changes in the variable's coding scheme beyond adding codes. Variable/ variable group deletions that are not performed at Level II may also be performed at this level. Level III data dictionary revisions will occur no more than twice in a five-year grant cycle to go

into effect at the beginning of a new grant cycle and mid-way through a grant cycle. The Project Directors may vote to suspend Level III changes for a partial or full cycle with justification, such as concern for data collection burden or some other scientific or pragmatic concern. Before the addition or deletion of variables, Project Directors from each site must listen in on a Form II interview to gauge current burden of data collection. The Level III data dictionary revision process involves the following steps (see accompanying 603 a Timeline for dates corresponding to steps for a particular TBIMS cycle):

a. Discussion of variable additions/deletions will begin 1 year prior to the final vote, variable piloting will start six months before the final vote, and the approved addition/deletion of variables will go into effect the quarter following the next data submission.

b. Requests for Level III revisions can originate in a SIG, Module or Committee. A SIG, Module, or Committee may propose a slate of variables or individual variables and must complete the Adding and Deleting Variables Form and submit to the Planning Committee 1 month after the Project Directors meeting where initial discussions took place.

c. The Planning Committee will summarize all proposed variable changes, email those to the TBIMS, and conduct a survey to determine any early questions/concerns with proposed changes 1 month after the Forms are due. Responses to that survey are due to the Planning Committee 2 weeks after receipt.

d. The Planning Committee will disseminate the survey results to the TBIMS 1 month after survey due date. The proposing SIG, Module or Committee will have to respond to any questions/concerns in writing to the Planning Committee 1 month later. The Planning Committee will disseminate any SIG, Module, Committee responses to the TBIMS 1 month after that.

e. The Project Directors will vote on which newly proposed variables should be piloted, and discuss any questions/concerns about variables proposed for deletion. Approval of new variables to be piloted must pass with a simple majority vote (9/16).

f. All approved variable groups and variables will be pilot tested by a sufficient number of centers (at least 3) with a sufficient number of cases to determine feasibility. The piloting will occur within the context of the currently approved variables in order to evaluate impact on length of interviews, burden to participants and data collectors, and redundancy perceived by participants. Adjustments to reduce or minimize burden should also be piloted. This activity will be coordinated by the NDSC and the proposing group, and will be completed 4 months after the proposed variable additions/deletions vote at the PD Meeting. Two weeks after variable data is submitted to the NDSC, a report will be made to the Planning Committee that will include a summary of data collected, cost estimates for collection along with any concerns or need for clarification. If an approved variable group or variable has already been pilot tested (meeting the definition above) in its proposed form (for example within a module), no further pilot testing is necessary.

g. The Planning Committee will immediately disseminate the report to the TBIMS, and conduct a survey to determine any final questions/concerns with proposed variable additions. Responses to the survey are due to the Planning Committee 2 weeks after receipt.

h. The Planning Committee will disseminate the survey results to the TBIMS 1 week after the survey due date. The proposing SIG, Module or Committee will have 2 weeks to respond to any final questions/concerns in writing to the Planning Committee. The Planning Committee will then disseminate any questions/concerns to the TBIMS 1 week after.

i. The Planning Committee will consolidate a list of candidate variables for addition and deletion and present this to the Project Directors for a super majority vote (11/16) on each variable change to be conducted at the Project Directors Meeting.

j. Variables being considered for addition/deletion for the beginning of a new grant cycle will be posted on the public website with the database data dictionary.

k. The NDSC will send a summary of variable changes and revised data collection forms to TBIMS centers within 1 month so they can submit these revisions for IRB approval.

l. At least 30 days prior to the changes going into effect, the NDSC will coordinate any necessary training for data collectors.

m. The approved changes will go into effect the quarter following the next data submission.

n. TBIMS centers and follow-up centers will begin using the revised forms, data entry, etc., as of the effective date.

4. **Off Cycle Changes to the National Database** are any proposed Level III changes to the National Database that deviate from the procedure described above.

   a. Off cycle changes should only be considered in the case of emerging scientific issues that arise, and must be acted upon outside of the regular Level III change cycle.

   b. Must be initiated through an existing committee, module or SIG.

   c. Provide a brief written proposal to the Planning Committee including a variable description, rationale, estimated burden on participants and data collectors. Also include the names of the sites willing to pilot the variables (at least 3 sites) with a prespecified number of participants that has been determined to be sufficient to assess feasibility.

   d. Planning committee votes on whether to proceed with piloting.

   e. Piloting is conducted. The piloting should occur within the context of the currently approved variables in order to evaluate impact on length of interviews, burden to participants and data collectors, and redundancy perceived by participants. Adjustments to reduce or minimize burden should also be piloted.

f. Summary of pilot results are sent to the Data Committee, who reviews and comments on any concerns raised by the pilot. The pilot results and Data Committee review are sent to the Planning Committee.

g. Planning committee votes.

h. If there is an affirmative vote from Planning Committee, the variable is added to the database.

i. At which time, the data collected in the pilot can be considered to be added to the National Database retrospectively.

j. The resources needed by all collaborating centers and the NDSC, and timeline for the proposed project should be clearly delineated.

Training requirements:

If new variables are being implemented, the SIG, Module or Committee recommending the new variables will be responsible for training data collectors on the collection of new variables. The NDSC will coordinate trainings.

Compliance:

All TBIMS centers, longitudinal follow-up centers and the NDSC are responsible for adhering to this policy and its procedures.

References:

None

History:

Date	Action
9/8/1999	Version used to create this SOP
9/16/2008	Transferred to SOP template
9/16/2008	SOP Review Committee Recommended moving sections related to changes to the national database syllabus from SOP 603a – Resolving Data Collection and Coding Questions SOP and sent to Planning Committee for review
12/4/2008	Approved by SOP Review Committee
12/12/2008	Approved by Planning Committee and Project Directors
6/17/2011	Added text to allow module groups to propose new variables and that approval of data additions/deletions to the database need a super majority vote (11/16).
1/29/2014	Revised level II and III procedure and added addendum/timeline for adding/deleting variables

Date	Action
3/21/18	Revised Level II and III procedures, added definitions, and added a provision for off-cycle changes
10/29/2018	Added requirement of PD listening in on Form II interview to item #3.
10/29/2018	Added to item 3f. - "The piloting will occur within the context of the currently approved variables in order to evaluate impact on length of interviews, burden to participants and data collectors, and redundancy perceived by participants. Adjustments to reduce or minimize burden should also be piloted."
10/29/2018	Added items b. through h. to item #4.
9/18/2023	Updated terminology and value codes; modified Level III revisions paragraph.

Review schedule:

At least every 5 years.

Recommendation for Adding/Deleting Variables from the National Database

Committee/Special Interest Group Completing the Form:

Contact Person:

Brief Description of the Variable:

1. What is the intent behind the addition of the variable? (Do not complete if variable is to be deleted.)

2. Does the variable to be added (or deleted) make a unique contribution as a covariate (i.e., predictor, modifier, mediator) across many important outcome variables?

3. Do the psychometric properties of this variable make it a "good" (or bad, for deletions) variable for measuring the construct of interest?

4. Is this variable of intrinsic importance as a long-term outcome?

5. The core national database was designed for critical long-term data collection where modules were designed to be time-limited data collection with specific research questions; does this variable support a research goal that cannot be met through a modular approach?

6. How "costly" (in terms of length of time and collection approach) is it to collect the proposed variable?

Timeline for Implementing Changes to the National Database

TASK	TIME FRAME	DATE Mid cycle variable changes	DATE End of cycle variable changes
Discussion of proposed variable additions/deletions	One year prior to the final vote	December 12th, 2023	June 17th, 2026
Com/Mod/SIG's proposing additions/deletions must complete "Adding and Deleting Variable" form and submit to Planning Committee	One month after Project Directors meeting where initial discussion took place	Jan 13th, 2024	July 18th, 2026
Planning Committee will summarize proposed variable changes, e-mail those to the TBIMS, and conduct a survey to determine questions/concerns with the proposed changes	One month after "Adding and Deleting Variable" forms are due	Feb 13th, 2024	August 18th, 2026
Responses to the survey are due	Two weeks after receipt of survey	Feb 27th, 2024	September 1st, 2026 (note: current NDSC funding ends September 30, 2026)
Planning Committee disseminates survey results to the TBIMS	One month after survey due date	March 27th, 2024	October 3rd, 2026
Com/Mod/SIG's respond to questions/concerns and send to Planning Committee	One month after survey results are disseminated	April 28th, 2024	November 3rd, 2026
Planning Committee disseminates all Com/Mod/SIG responses to the TBIMS	One month after responses to questions/concerns are due	May 28th, 2024	December 5th, 2026
During the June (for mid cycle changes) December (for end of cycle changes) meeting Project Directors will vote on which newly proposed variables should be piloted and discuss any questions/concerns about variables proposed for deletion	Roughly six months after first discussion of proposed variable additions/deletions	June 26th, 2024	December 15th, 2026
Variable pilot testing	Four months after the proposed variable additions/deletions vote at the PD Meeting	June 26th, 2024 – October 24th, 2024	December 15th, 2026 – April 17th, 2027
All variable data must be sent to NDSC	End date of pilot testing	Oct 24th, 2024	April 17th, 2027
NDSC will create report and give to Planning Committee - Planning Committee disseminates report to TBIMS along with a survey to determine any final questions/concerns	Two weeks after variable data is submitted to the NDSC	Nov 7th, 2024	May 1st, 2027
Responses to the survey are due	Two weeks after receipt of survey	Nov 21th, 2024	May 15th, 2027

TASK	TIME FRAME	DATE Mid cycle variable changes	DATE End of cycle variable changes
Planning Committee disseminates survey results to the TBIMS	One week after survey due date	Nov 28th, 2024	May 22nd, 2027
Proposing Com/Mod/SIG's will respond to final questions/concerns and present them at December PD Meeting (for mid cycle changes)	Two weeks after responses to questions/concerns are due	Dec 11th, 2024	
Com/Mod/SIG's respond to final questions/concerns and send to Planning Committee	Two weeks after survey results are disseminated		June 5th, 2027
Planning Committee disseminates all Com/Mod/SIG responses to the TBIMS	One week after responses to questions/concerns are due		June 12th, 2027
Final vote for variable additions/deletions at June PD Meeting (for end of cycle changes)			June 16th or 23rd, 2027 (TBD)
New variables implemented	The quarter following the next data submission	April 1st, 2025	October 1st, 2027

OP004	TBIMS Committees, Modules and Special Interest Groups, and Election Process for Committee Chairs and Co-Chairs
Review Committee: Planning	Start Date: 9/14/2009
Addendum: TBIMS SIG Definitions	Last Revised Date: 12/13/22
Forms: None	Last Reviewed Date: 12/1/22

Introduction:

There exists within the TBIMS, Committees, Modules and SIGs. Five standing committees exist with different functions: Data, Knowledge Translation, Planning, Research, and the Executive Committee. Committee chairs and co-chairs are elected during the first Project Directors Meeting following the beginning of a new TBIMS grant cycle, or as needed due to vacancy. A formal procedure has been implemented to ensure a fair election process. Modules are time limited peer reviewed studies involving more than one TBIMS. SIGs are groups of TBIMS investigators with common interests in specific topics related to TBI. The current SIGs are: Sleep-Wake-Fatigue, Disorders of Consciousness, Chronic Brain Injury, VA Collaborative, **Inclusion, Diversity, Equity, and Accessibility (IDEA)** SIG, Analytic SIG, Health Services and Implementation Science SIG, Behavioral Health SIG, Geographic Indicators SIG, and the Caregiver and Family SIG (see addendum: TBIMS SIG Definitions).

Purpose:

To describe the purpose, formation and function of the TBIMS Committees, Modules, and SIGs. To establish a formal method to elect committee chairs and co-chairs of the Executive, Planning, Research, Knowledge Translation, and Data committees and any other committees created in the future.

Scope:

All TBIMS Centers, TBIMS Follow-up Centers and NDSC.

Responsibilities:

The TBIMS, TBIMS Follow-up Centers and NDSC will abide by this policy and procedure.

Committees Descriptions:

Executive Committee – The purpose of this committee is to provide guidance to NIDILRR and the TBIMS Project Directors regarding key issues facing the TBIMS and to establish regular communication with the director of NIDILRR. This committee consists of the chairs or co-chairs of each of the standing Committees (Planning, Research, Data, Knowledge Translation), the Director of the NDSC, a representative of the VA collaborative group, the NIDILRR TBIMS Program Manager, and the Executive Committee chair. The Executive Committee chair is

elected by majority vote of the Project Directors from each TBIMS at the beginning of each grant cycle before the election of Committee chairs and co-chairs and serves for the 5-year grant cycle. The chair does not have to be a Project Director, but must be in a leadership role within a currently NIDILRR funded TBIMS center. To achieve broad representation from the funded centers, members of the Executive Committee must represent at least 4 NIDILRR funded TBIMS centers (not counting NDSC representatives from a center that is funded as both NDSC and a TBIMS center). If elections of committee chairs naturally results in less than 4 NIDILRR funded TBIMS centers, the Planning Committee will convene and review membership and make recommendations to ensure broader representation of centers on the Executive Committee. This may involve appointing or electing a member at large who is not affiliated with a center already represented. The Executive Committee sets the agenda for the semi-annual Project Directors meetings. The chair of the Executive Committee chairs the semi-annual TBIMS Project Directors' Meetings. There is no co-chair for the Executive Committee. Committee support is provided by the NDSC.

Strategic Planning Committee – The purpose of this committee is to provide strategic, long-term planning for the TBIMS research endeavors, including collaboration with other programs and agencies outside and inside NIDILRR. This also entails assisting with the development and direction of Special Interest Groups among the TBIMS Centers. It leads the process of reviewing and recommending major revisions to the core National Database variables (adding and deleting variables) twice during a funding cycle. It is responsible for providing guidance on other significant issues related to the scope of the TBIMS such as National Database inclusion criteria, data quality targets, and oversight of the Standard Operating Procedures Manual (SOP). The Planning Committee consists of the Project Director from each TBIMS Center or a designated person from that center if the Project Director is absent. Each center carries a single vote.

Data Committee – The purpose of this committee is to oversee all issues related to data collection, management and quality for the TBIMS National Database. This includes setting and reviewing data quality targets and reporting to the Project Directors on issues relating to enrollment, follow-up, and missing data. This committee also reports to the Project Directors on concerns from data collectors/managers/center staff regarding data quality and collection (burden, complexity, reliability, et cetera). In addition, the Data Committee assists the NDSC with data coding and training issues. A subgroup of "Databusters" assists in the resolution of variable data collection issues that cannot be resolved by the Data Committee or the NDSC. The committee also proposes coding clarifications/changes to the Project Directors, coordinates with the NDSC on the use and development of software for data entry and reports, reviews all existing and new data error checks, and oversees data collection certification activities (Form I, Form II, DRS, CT scan). Coordination of piloting proposed variables is another responsibility.

Research Committee – The purpose of this committee is to foster research utilizing TBIMS data by facilitating collaboration and cooperation among TBIMS Centers and between external researchers and TBIMS Centers. With NIDILRR's input, the committee is responsible for developing SOP 602f - Access to the TBIMS National Database for those utilizing the national database, and for updating the policy as needed. The committee is responsible for reviewing requests by external investigators or organizations to use TBIMS data, as well as reviewing and providing feedback on module studies that are initiated by TBIMS Centers during the funding cycle, but have not undergone external peer review. Such module proposals will be reviewed by the research committee and then forwarded on to NIDILRR staff for review. The Research

Committee will also be responsible for overseeing solicitation of manuscripts eligible for the Rosenthal Research Award, and for reviewing and choosing papers for this award. Finally, the research committee will oversee discussion of variables recommended for pilot testing for addition to the national database as well as overseeing discussion of modification of existing variables to address research questions, with the goal of ensuring the scientific integrity of the data.

Knowledge Translation Committee – The purpose of this committee is to expand upon past dissemination activities by reaching out to a broader community including consumers, local/state/national and international societies and interest groups involved in the treatment and care of individuals with TBI. It is the primary conduit to the Model Systems Knowledge Translation Center. It pursues and coordinates the development of special TBIMS-focused issues of relevant journals and TBIMS presentations at relevant conferences. It reviews and makes recommendations for revisions of the TBIMS slide show, and other TBIMS related products (e.g., fact sheets, brochures, etc.).

Committee Formation and Function:

The Executive and Planning Committees are formed as described above. For the Data, Research, and Knowledge Translation Committees, each funded center has the option of appointing someone to the committee; the members need not be Project Directors, and representation can vary from one meeting to the next. However, each center is encouraged to designate one person to represent that center at committee meetings.

Meetings are open and anyone can contribute to the discussion and recommend agenda items. Access to the committee listserv is open. However, each center represented on the committee has only one vote, which is also the case in web-voting. At the beginning of a new TBIMS grant cycle, each committee must appoint a chair and co-chair by majority vote of committee members. All committee chairs and co-chairs must be from a currently funded TBIMS Center. The committee chairs develop their meeting agendas (teleconference or in-person) and lead those meetings. The co-chairs take meeting minutes and function as the chair in the absence of the chair. The committees meet in- person at the semi-annual TBIMS Project Directors' Meetings and via teleconference at other times as needed. Other committee work is completed via committee listservs.

Minutes from all meetings are posted on the NDSC website (www.tbindsc.org).

Procedural Steps for Committee Election of Chairs and Co-Chairs:

All committee chairs and co-chairs will be elected during the first Project Directors (PD) Meeting following the beginning of a new TBIMS grant cycle or at any time there is a chair or co-chair vacancy. The nomination and election process is outlined in the following steps:

1. See above committee descriptions and committee form and function section for descriptions of who is eligible to serve as chairs and co-chairs.
2. The NDSC will request that each Center email their named member of each standing committee (Data, KT, Research, Planning – is automatically the Project Director of their TBIMS), and any staff eligible to be nominated for Chair of the Executive Committee.
3. The NDSC will update all Committee listservs with new standing committee membership.

4. One month prior to the PD Meeting, the NDSC will post an email to all TBIMS Committee listservs, requesting confidential nominations including self-nominations for Chair of the Executive Committee and chair and co-chair for each of the four standing committees with the list of those eligible for each position, and a deadline for submitting nominations. An individual can be nominated for more than one position if they are eligible.
5. The NDSC will contact all nominees to determine their interest in serving in the nominated position(s).
6. The NDSC will notify each TBIMS Project Director of any nominations from their Center.
7. The NDSC will create and post the final ballot for each position to all TBIMS Committee listservs and include it in the meeting electronic binder.
8. The Executive Committee chair will be elected during the Planning Committee meeting at the PD Meeting and all other committee chairs and co-chairs will be elected during their committee meetings at the PD Meeting.
    a. If a person who has been nominated to more than one position is subsequently elected to more than one position, that person may choose which Chair position they accept. They may only accept one. The exception to this rule is if a person is elected to chair the Executive Committee and another committee. In this case, election to chair the Executive Committee would surpass election to chair the other committee.
9. When electing the chair of the Executive Committee, each Project Director will have one vote. When electing Committee chairs and co-chairs, each Center represented at the Committee meeting will have one vote.
10. Votes will be cast by secret ballot using the Hare System. https://sof.sites.uchicago.edu/page/hare-system-proportional-representation. See addendum The Hare System of Proportional Representation.
11. Votes will be tallied by a member of the NDSC to assure confidentiality.
12. For committees, once the chair has been elected a new round of voting will be conducted to elect the co-chair using the same procedures as used for the chair.
13. The newly elected Chairs and Co-chairs will assume their role immediately following the December Project Directors meeting.

Modules:

Modules are time limited studies involving more than one TBIMS Center and are generally observational in nature focused on a specific aspect of TBI. These studies generally start at the beginning of each new TBIMS grant cycle and are intended to conclude prior to the end of the same grant cycle. For the 2017-2022 grant cycle, each TBIMS proposed a module study as part of their TBIMS application, then a voting process led by NIDILRR staff was used to decide which modules would be chosen for implementation with the lead center being the one that had proposed the module. Each TBIMS Center was required to participate in at least one module study. Modules can also be implemented during the grant cycle. Please see SOP 700g - Module Project Peer Review Procedures for further detail on the internal module peer review process. Module data collection can be supported by the NDSC. Each module has its own listserv.

Special Interest Groups:

SIGs can be formed at any time and focus on topics of interest to TBIMS investigators. New SIGs will be allotted meeting slots at two consecutive Project Directors Meetings, after which time SIGs must have regularly scheduled conference calls (with documented minutes) to ensure continual progress outside of the Project Directors Meetings. The allocation of continued meeting time at semiannual meetings will be at the discretion of the Executive Committee.

Training requirements:

None

Compliance:

All TBIMS Centers, TBIMS Follow-up Centers and NDSC will comply with this policy and its procedures.

References:

None

History:

Date	Action
9/14/2009	SOP drafted
1/9/2013	On page 3 under "Formation and Function" a sentence was added to clarify that committee chairs and co-chairs must be from a currently funded TBIMS Center
1/10/2013	The title of the "Dissemination Committee" was changed to "Knowledge Translation Committee."
3/13/2013	An addendum that provides a description of each SIG was added to the SOP
3/13/2013	On page 2 it was noted that if the NDSC resides at a currently funded TBIMS Center a representative of that Center is permitted to serve on the Executive Committee along with the NDSC representative
6/12/2015	Updated NIDRR to NIDILRR
11/17/2016	Clarified policy to state EC chair can only be from a NIDILRR funded TBIMS. Added a representative from the VA collaborative group to the EC committee. Added the Caregiver and Family SIG.

Date	Action
12/5/2019	Moved SOP 609 - Nomination Process for Committee Chairs and Co-Chairs and instructions into this SOP. Five Year review completed with minor revisions/updates.
12/9/2019	Changed name of Aging with TBI and TBI in the Elderly SIG to the Chronic Brain Injury SIG.
8/23/2021	Changed name of Cultural Issues SIG to the Inclusion, Diversity, Equity, and Accessibility (IDEA) SIG and added their new mission/objectives.
11/17/2022	Added clarification for the case of a person being nominated and elected to more than one position.
12/13/2022	Removed language regarding not having more than one representative from each center on the Executive Committee; replaced it with having at least four centers represented.

Review schedule:

At least every 5 years.

Addendum

TBI Model Systems

Special Interest Group Definitions

Sleep-Wake-Fatigue SIG

The focus of the Sleep-Wake-Fatigue SIG is to facilitate collaborative projects in this domain. Currently two areas of focus include diagnosis and management of acute and post-acute sleep, wake, and fatigue disorders. Currently, members are participating in developing research proposals and data analysis from TBIMS associated projects. Dissemination to providers and consumers and addressing compliance with treatment are also areas of interest. Finally, members share methodologies and other research challenges with advancing the science in this arena with TBI survivors.

Disorders of Consciousness SIG

The DOC SIG was established to promote collaborative research on prognosis, assessment, and treatment of individuals with disorders of consciousness and to facilitate translation of this research into policy and practice. The TBIMS DOC SIG works in collaboration with the DOC Task Force of the Brain Injury Special Interest Group of the ACRM, on shared missions, and also pursues TBIMS-specific missions individually.

Objectives:

1) To support the conduct of new research and synthesis of existing research to enhance the evidence base on which prognostic, assessment, and treatment decisions for this population can be made.
2) To engage in advocacy for appropriate rehabilitation services for individuals with DOC, based on emerging evidence.
3) To serve as expert consultants and resources to other researchers, clinicians, and policy makers dealing with the DOC population.

Chronic Brain Injury SIG

The Chronic Brain Injury SIG supports the use of the TBI Model System infrastructure (investigators, data, modules, relationships) to move the field forward in the understanding and care of chronic brain injury. The Chronic Brain injury SIG uses mechanisms such as peer-reviewed research publications, development of practice guidelines, provider and consumer-focused knowledge translation, presentations, advocacy, experts consultation, advocacy, and policy promotion to achieve its purposes. The Chronic Brain Injury SIG attends to the TBI Model Systems national database representativeness, variables, and research needs relative to Chronic Brain Injury, and uses the TBIMS longitudinal database to answer research questions. This includes the promotion of collaborative research on lifelong living with brain injury, outcome trajectories, and TBI among the elderly.

VA Collaborative SIG

The Department of Veterans Affairs Collaborative SIG was established to explore opportunities for collaborative research between the NIDILRR and VA PRC TBI Model Systems. The SIG facilitates discussion and collaboration around topics of mutual interest between the NIDILRR

TBIMS and VA TBIMS. VA Collaborative SIG members propose, execute, and review research projects between NIDILRR and VA PRC TBIMS centers. This review has allowed for sharing best practices for overcoming barriers to collaboration such as data security requirements, formation of collaborators, and funding rules on VA-funded grants.

Inclusion, Diversity, Equity, and Accessibility (IDEA) SIG

Mission/Objectives:

1) To serve as a resource group for facilitation of inclusion, diversity, equity, and accessibility within TBIMS research, including hypothesis generation, data collection and analysis, participant enrollment and retention, interpretation of data, and knowledge translation, and working with the National Data and Statistical Center and Model Systems Knowledge Translation Center as appropriate to achieve these goals.
2) To facilitate development of prospective collaborative research projects that address issues of inclusion, diversity, equity, and accessibility in rehabilitation and outcomes for persons with TBI.
3) To disseminate materials and translate knowledge that promotes inclusion, diversity, equity, and accessibility with regard to assessment and treatment of persons with TBI.
4) To advocate for inclusion, diversity, equity, and accessibility in all aspects of TBI-related research and clinical practice.

Analytic SIG

The main purpose of the Analytic SIG is to serve. Specifically, we are motivated to provide both current and advanced statistical and psychometric support to researchers and clinicians alike within the TBIMS. The main focus of the support will be general education which will be used as a conduit for dissemination of contemporary methodologies designed to enhance research in rehabilitation at all levels.

Objectives:

1) Inform TBIMS researchers about the latest advances in data analysis and measurement methods through regular presentations at TBIMS meetings
2) Provide a forum for in depth discussion of data analysis and measurement methods with the TBIMS
3) Inform TBIMS researchers about educational opportunities including current publications relevant to understanding the latest advances in data analysis and measurement methods
4) Identify and prioritize topics on analysis and measurement methods for knowledge dissemination within the TBIMS
5) Share knowledge gained through the SIG outside of the TBIMS through presentation at other meetings and publication

Caregiver and Family SIG

Purpose: To explore research opportunities, variables, methodology, and collaborative projects that address caregiver and family issues related to TBI.

Mission: The Caregiver and Family SIG will develop retrospective data analyses and prospective studies to further advance the knowledge of the impact of TBI on caregivers and the relationship of caregiver functioning to outcomes in persons with TBI, including both military and civilian

populations. The SIG will also focus on developing treatment protocols targeted at reducing distress and improving functioning for caregivers in both military and civilian populations.

Health Services and Implementation Science SIG

Purpose: The purpose of this SIG is to engage TBIMS researchers in projects that fall into the realm of Health Services Research and/or Implementation Science.

Mission: To increase the engagement of the TBIMS in research that can have a more immediate impact on healthcare services, and to study how to best implement findings from TBIMS research.

Rationale: Health Services Research. . . "is the multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and ultimately our health and well-being. Its research domains are individuals, families, organizations, institutions, communities, and populations" (Academy for Health Services Research and Health Policy, 2000). Implementation Science is the "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services" (Eccles, 2006). We will educate ourselves about the focus and design of projects that fall in these areas, with the eventual goal of designing collaborative study proposals.

Behavioral Health SIG

The overarching mission of the Behavioral Health SIG is to promote health and community integration in persons with TBI through advances in research, clinical care, and advocacy for behavioral health issues. Behavioral health in this context refers to topics including health behaviors, mental health, substance use, resilience, and well-being.

The Behavioral Health SIG will facilitate collaborative efforts to improve understanding of these topics. As such, SIG activities will include, but will not be limited to, the following:

1) Forming collaborative projects utilizing existing NIDILRR and VA TBIMS national database behavioral health variables.
2) Identifying and promoting new behavioral health variables within the NIDILRR and VA TBIMS national databases.
3) Organizing efforts for grant funding focused on behavioral health within TBI populations
4) Advocating for behavioral health best practices within rehabilitation settings. Consulting and collaborating with other researchers, care providers, professional organizations, and research groups to address behavioral health topics.

Geographic Indicators Special Interest Group (GeoSIG)

Purpose: To explore research opportunities, methods, and collaborative projects that incorporate geographic indicators into studies of TBI outcomes.

Activities:

1) Provide a forum for interested TBIMS researchers to enhance their knowledge of geographic indicators and use in research.
2) Serve as a vehicle to share opportunities for collaborative projects.

3) Propose and maintain an indicator of neighborhood socioeconomic status that can be incorporated into the TBIMS National Database.
4) Identify indices of the social determinants of health that could be utilized by TBIMS researchers.
5) Provide training opportunities for TBIMS researchers who are not members of the GeoSIG to understand how geographic indicators could be incorporated into their research.

Addendum

The Hare System of Proportional Representation

PURPOSE

The Hare System is intended to secure the representation of every shade of the electorate's opinion in direct proportion to its numerical strength.

WHAT IT SEEKS TO RECTIFY

Under the usual form of voting for a list of people for a committee or representative body where several are to be chosen, a bare majority of the votes or even a plurality is sufficient to elect. The outstanding example of this system is the method used in this country for presidential electors. Equally glaring is the inequality where but one person is chosen to office in a representative assembly. The following example of a congressional election in Indiana indicates this:

Party	Votes	Representatives Elected
Democratic	291,288	13
Republican	166,698	0
Progressives	127,041	0
Others	55,807	0

In this instance, while 349,546 voters, a majority, went without representation, a minority elected all the representatives. This occurs with considerable frequency in American legislative elections.

THE MECHANICS OF THE HARE SYSTEM

Nominations

Nominations are made by a petition signed by a stated number of voters. Candidates for the Council of the University Senate are placed in nomination by three or more members of the Senate. Any number of nominations may be made regardless of the number to be elected.

The Ballot and Method of Voting

A sample ballot is as follows: Sample Ballot Directions to Voters

Put the figure 1 in front of the name of your first choice. If you want to express additional choices, do so by putting the figure 2 in front of the name of your second choice, the figure 3 in front of the name of your third choice, and so on. You may express as many choices as you please, without regard to the number to be elected.

Your ballot will be counted for your first choice if it can help him or her. If it cannot help your first choice, it will be transferred to the first of your remaining choices whom it can help. You cannot hurt any of your favorites by marking lower choices for others. The more choices you express, the surer you are to have your ballot count for one of them. But do not feel obliged to express choices that you do not really have.

A ballot is spoiled if the figure 1 is put opposite more than one name or if checks are used instead of numerals to indicate choices. See the following example:

2 Jones Smith

1 Brown

5 Black

3 Green Grey

4 Wood Stone Clark Etc.

The voter in the above case has voted for five candidates in the order of his or her preference. The voter has said, in effect, "Brown is my first choice, but if she is not chosen, or if he already has enough votes to elect, I desire that you count my second choice, Jones, and so on down the list."

The Counting of the Ballots: The Quota

The first step in counting the ballots is to ascertain the number of first choices necessary to elect a candidate. This is obtained by the following formula:

the number of votes cast divided by (the number to be elected + 1) + 1 = quota

For example, in an election in which there were 425 votes cast in balloting to elect 17 members on one ballot, the quota would be:

425

17 + 1 +1 = 24

Remaining fractions are always discarded. The quota of 24 represents the least number of first choices a candidate may receive and still be declared elected. The extra "1" is added (after the division) because, without it, the quota would be 23, making it possible for 18 candidates each to receive 23 votes, when only 17 are to be elected.

The Counting of the Ballots: The Transfer of Votes

The ballots are divided into piles according to the first choices indicated. It will then be found, we may suppose, that 27 have marked Jones as the first choice, that 25 have marked Brown as first choice, etc. In tabular fashion, the results might be as follows, according to the first choices marked:

27 Jones

25 Brown

14 Black

23 Green

16 Wood

Jones and Brown, having secured the quota of 24, are declared elected.

Jones has 3 more votes than needed for election. As these three ballots can no longer help Jones to be elected, they are transferred to help elect other candidates. Thus, the three ballots are

transferred to the second choices indicated on each. If any of these second choices are for Brown, who also has already been elected, the third choice is given the ballot instead.

Brown's extra votes (i.e., those in excess of 24), are then distributed according to second choice, et cetera.

If there are vacancies and if there are no surpluses, all the votes of the candidates securing the lowest numbers are taken from them, there being little chance of their election, and they are distributed according to their second or third or fourth choices, and so on.

OP005 Procedure for Creating and Changing SOPs

Review Committee: Planning	Effective Date: 11/04/2011
Attachments: None	Revised Date: 6/12/2015
Forms: Template available at NDSC	Reviewed Date: 12/05/2019

Introduction:

The Standard Operating Procedure (SOP) Manual was created to implement Traumatic Brain Injury Model Systems (TBIMS) policies and procedures using a formal approach. SOPs must be developed, changed, and finalized using the specific procedural steps outlined below.

Purpose:

To establish a formal method to develop, change, and finalize a Standard Operating Procedure (SOP).

Scope:

The TBIMS Centers and the National Data and Statistical Center (NDSC).

Responsibilities:

Staff of the TBIMS Centers and the NDSC must abide by this procedure.

Procedural steps:

Creating a New SOP:

1. The NDSC coordinates the administrative aspects of developing new SOPs.
2. A New SOP must originate from either the NDSC or a specific TBIMS Committee (Executive, Planning, Data, Knowledge Translation, or Research) which will complete the SOP template available at the NDSC.
3. Once the SOP template is completed in draft form, it needs a majority approval by the originating committee members. If the SOP originates from the NDSC it still must go through an originating committee before advancing ahead in the SOP process.
4. Once approved by the originating committee the SOP goes to the Planning Committee and to NIDILRR for additional vetting. All edits and contextual changes will be taken into consideration during this stage and tracked using MS Word track changes.
5. After approval by majority vote is received from the Planning Committee the SOP goes into effect on the effective date displayed in the header and will be posted to the NDSC web-site.
6. The group where the SOP originated will review the SOP on its normal schedule (listed at the bottom of the SOP).

Making Changes to Existing SOPs:

1. The NDSC will coordinate the administrative aspects of changing existing SOPs.
2. If an SOP is to be revised it goes to the TBIMS committee from where it originated. [Note: Any SOP without an originating committee will be assigned to a committee by the Executive Committee].
3. Once the SOP has been revised and receives a majority vote by the originating committee the SOP along with a short paragraph outlining the contextual changes to the SOP is sent to the Planning Committee and to NIDILRR for additional vetting. All edits and contextual changes will be taken into consideration during this stage and tracked using MS Word track changes.
4. After approval by majority vote is received from the Planning Committee the SOP goes into effect on the effective date displayed in the header and will be posted to the NDSC web-site.
5. The group where the SOP originated will review the SOP on its normal schedule (listed at the bottom of the SOP).

Training requirements:

None

Compliance:

Staff of the TBIMS centers and the NDSC must comply with this procedure.

References:

None

History:

Date	Action
11/4/2011	SOP developed by the NDSC
5/15/2012	The form "SOP Review Committees" was listed as an attachment
1/1/2013	"Review Committee" was added to the heading. Review Committee Attachment deleted
4/16/2015	Updated "Dissemination" to "Knowledge Translation"
6/12/2015	Updated NIDRR to NIDILRR

Review schedule:

At least every 5 years.

SOP Template	
Review Committee: (Data, NDSC, Planning or Research)	Start Date: XX/XX/XXXX
Attachments:	Last Revised Date: XX/XX/XXXX
Forms:	Last Reviewed Date: XX/XX/XXXX

Introduction:

Make sure you use the Heading 1 style for the Introduction, Purpose, Scope, Responsibilities, Procedural Steps, etc. Use the Normal style for regular text. Once complete, make sure the properties pages are filled out.

Author = NDSC

Title = Number - Title

Subject = Heading tab

Keywords = as appropriate

Status = Final/Draft

Comments = Introduction

Purpose:

Provide intention of this SOP.

Scope:

Describe whom this SOP affects.

Responsibilities:

Describe who is responsible for following the details of this SOP, and a broad summary of what those responsibilities are.

Procedural steps:

Training requirements:

Compliance:

References:

History:

Date	Action
x/x/xxxx	SOP drafted

Review Schedule:

At least every 5 years.

OP006	Branding and Authorship of Manuscripts and other Products using Data from the TBIMS National Database, Archived Collaborative Module Study Databases, and Ongoing TBIMS Module Studies
Review Committee: Research	Start Date: 5/1/2012
Attachments: None	Last Revised Date: 9/20/2023
Forms: None	Last Reviewed Date: 12/7/2019

Introduction:

This policy and procedure addresses the issues of branding with the Traumatic Brain Injury Model Systems name, as well as authorship of manuscripts, abstracts and other reports using data from the Traumatic Brain Injury Model Systems (TBIMS) National Database, Archived Collaborative Module Study Databases, and ongoing TBIMS Module Studies (referred to as "TBIMS manuscripts" and "TBIMS publications" throughout this document). This also refers to any epubs or digital manuscripts.

Purpose:

To provide guidance for branding of TBIMS publications and for determining/assigning authorship on manuscripts and other reports that use data from the TBIMS National Database, Archived Collaborative Module Study Databases, and ongoing TBIMS Module Studies.

Scope:

- Staff of the TBIMS Centers: All staff, students, and other related personnel involved in the NIDILRR-funded TBI Model Systems Centers who wish to use data from the TBIMS National Database, Archived Collaborative Module Study Databases, and ongoing TBIMS Module Studies.
- Staff of the previously funded TBIMS Centers that are currently funded as TBIMS Longitudinal Follow-Up Centers.
- Staff of non-TBIMS entities that have been designated as formal collaborators per SOP *DS004 Policy and Procedure for Collaborative Relationships between TBIMS and Non-TBIMS Entities*.

Note: This does not apply to public uses (i.e., external requests to utilize data of the TBIMS National Database or Archived Collaborative Module Study Databases). These users should follow the guidelines for acknowledgment of the TBIMS that is outlined in SOP DSF201 "External Notification Policy and Procedure for TBI Model Systems National Database Research", and American Psychological Association (APA) or International Committee of Medical Journal Editors (ICMJE) guidelines for authorship.

Responsibilities:

All persons identified in the "Scope" statement will abide by this policy.

Policy:

I. TBIMS Branding:

a. Branding of a study with the TBIMS name is required if the data used is from the TBIMS National Database or from a TBIMS Module Study.

b. Method of branding: The words "Traumatic Brain Injury Model Systems" should appear somewhere in the title or in the author byline. It is the discretion of the authors how to implement this, within the requirements/guidelines of the journal or organization to which a manuscript/report is submitted. It is suggested that NIDILRR also be included. NIDILRR may be abbreviated rather than spelled out. Some possibilities follow:

i. "_____: A NIDILRR Traumatic Brain Injury Model Systems Study."

ii. "A NIDILRR Traumatic Brain Injury Model Systems Investigation of _____."

iii. Bell, K….. and the NIDILRR Traumatic Brain Injury Model Systems Headache Module Study Group. (The identities of members of the group who are not listed in the byline can be given in a footnote or endnote to the byline, or in the Acknowledgments, depending on journal requirements.)

c. The following acknowledgement should be included:

"The contents of this (insert type of publication; e.g., book, report, film) were developed under a grant from the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR grant number 90XXXXXX). NIDILRR is a Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of this (insert type of publication; e.g., book, report, film) do not necessarily represent the policy of NIDILRR, ACL, HHS, and you should not assume endorsement by the Federal Government."

d. Any manuscript, poster, presentation, and other product 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: ____ [insert year of data release]

URL: http://www.tbindsc.org

Version: https://osf.io/a4xzb/

e. Use of branding can be waived if the journal to which the manuscript is being submitted does not allow it.

f. Authors of a study using only local data, that was funded by their local TBIMS grant, may use the TBIMS branding if desired, but are not required to do so.

II. Authorship of manuscripts using data from the TBIMS National Database, Archived Collaborative Module Study Databases, and ongoing TBIMS Module Studies:

a. Authorship should be based on a substantive contribution to the manuscript. The following guidelines, proposed as a standard by the ICMJE, are to be applied on TBIMS manuscripts.

i. Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.

ii. When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship/contributorship defined above, and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms. When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Journals generally list other members of the group (i.e., non-authors) in the Acknowledgments. The NLM indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript; it also lists the names of collaborators if they are listed in Acknowledgments.

iii. Acquisition of funding, collection of data, or general supervision of the research group or of local data collectors alone does not constitute authorship.

iv. All persons designated as authors should qualify for authorship per the three criteria provided above, and all of those who qualify per the three criteria provided above should be listed as an author.

v. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

vi. All contributors who do not meet the criteria for authorship may be listed in an Acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chairperson who provided only general support.

vii. Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under such headings as “clinical investigators” or “participating investigators,” and their function or contribution should be described—for example, “served as scientific advisors,” “critically reviewed the study proposal,” “collected data,” or “provided and cared for study patients.” Because readers may infer their

endorsement of the data and conclusions, these persons must give written permission to be acknowledged.

b. The primary author of the TBIMS manuscript has the responsibility to ensure that each co-author listed has made a contribution substantial enough to warrant authorship, and all persons who deserve authorship are listed as an author.
c. It is suggested that issues of authorship and of acknowledgment of collaborators be discussed as soon as group members (interested in publishing a paper on a specific topic) have been identified, via the TBIMS Notification process. It is recommended that those interested in collaborating on a notification specify what authorship-qualifying contributions they intend to make. Upon finalization of the notification output (e.g., manuscript, presentation, etc.), it is recommended that those interested in being listed as authors specify what authorship-qualifying contributions they have made. In the case of TBIMS manuscripts, opportunities for "substantial contributions to conception and design, acquisition of data" are limited. Furthermore, only a limited number of people can realistically make a meaningful contribution to the "analysis and interpretation of data". Journals have begun to limit the number of authors and/or to ask for specific declarations of the contribution of each proposed author, so as to decrease incidents of authorship inflation. TBIMS investigators should heed the letter and the spirit of the APA and ICMJE authorship requirements. Those who have not met authorship requirements should decline authorship; those who have participated in some capacity but who have not met authorship requirements can be listed in the acknowledgements.

Training requirements:

None

Compliance:

All persons identified in the "Scope" statement must comply with this procedure.

References:

http://www.icmje.org/ethical_1author.html

History:

Date	Action
5/1/2012	New Policy Approved by Project Directors
6/1/2015	Revised acknowledgement language to include NIDILRR, ACL and the Department of Health and Human Services
12/7/2019	Full review completed
2/18/2021	Added required use of citation for the TBIMS National Database and clarified other SOP language

Date	Action
9/20/2023	Added language regarding authorship-qualifying contributions

Review schedule:

At least every 5 years.

OP007 Adding Affiliate Hospitals to a TBI Model System

Review Committee: Planning	Start Date: 12/1/2016
Addendum: None	Last Revised Date: 6/1/2023
Forms: None	Last Reviewed Date: 6/1/2023

Introduction:

In order for a patient to be eligible for enrollment in the TBIMS National Database (NDB), he/she must receive both acute care and comprehensive rehabilitation in facilities that are a part of the system of care of a TBIMS Center. Historically, the facilities associated with a Center's system of care are named in the grant application of the funded Center.

For an acute care hospital (trauma center) to be eligible for inclusion in a Center's system of care, the following criteria must be met:

- All required Form 1 data elements must be available for abstraction from the rehabilitation medical record or participant information access must be sufficient so that these data elements can be collected by appropriately trained research assistants.
- This access may be provided due to the acute care hospital being part of the same system of care, a formal contract, a letter of agreement, inclusion of acute care physician(s) as co-investigator(s), or some other durable agreement that will ensure uninterrupted, timely access to all needed data elements.

For a rehabilitation facility to be eligible for inclusion in a Center's system of care, the following criteria (defined in SOP DA001 "Identification of Subjects for the TBIMS National Database") must be met:

- The facility (hospital, rehabilitation unit/hospital, hospital-based skilled nursing facility, skilled nursing facility, or a long-term acute care hospital) must provide comprehensive rehabilitation.
- Medical and rehabilitation care must be supervised by a TBIMS-affiliated physician and must have 24-hour nursing care. Affiliated physicians may or may not be co-investigators for the TBIMS project; thus, the physician's role may be clinical only or may include active participation in research.
- These rehabilitation therapies (PT, OT, Speech, Rehabilitation Psychology/Clinical Neuropsychology, and/or family support/education) must be provided to patients.
- The rehabilitation program must operate in a manner consistent with (a) CARF standards for brain injury inpatient rehabilitation and/or (b) Medicare requirements for inpatient rehabilitation.
- All data required by the National Database are accessible and transferable to the NDSC with appropriate informed consent.

There has been an increasing desire for TBIMS Centers to add affiliate hospitals or facilities (AF) to their system of care after the start of the performance period of the grant. One reason to

add an AF is to assist the TBIMS in meeting the minimum number of enrollees in the NDB. There is a need to develop guidelines for adding facilities to an existing Center's system of care.

An AF is defined as a facility that is added to an existing TBIMS Center's system of care and that meets the requirements listed in the Introduction above. An AF can be any type of inpatient facility where individuals with TBI are cared for along the continuum of care from time of injury through discharge from inpatient rehabilitation (e.g., acute care hospital/unit, long term acute hospital/unit, rehabilitation hospital/unit, nursing home, et cetera).

Purpose:

To provide guidelines for adding AF to a TBIMS during a grant funding period, while maintaining data quality.

Scope:

All TBIMS Centers.

Responsibilities:

All TBIMS Centers are responsible for adhering to this policy and its procedures.

Procedural steps:

1) The TBIMS Center that wishes to add an AF to their existing system of care must send a request to their NIDILRR Project Officer. The request must:

- Briefly describe the facility, the facility's capacity to provide services for individuals with TBI (trauma center level, approximate number of persons with moderate/severe TBI seen per year, and any other pertinent information), and the reason for adding this facility to the system of care.
- Specify the arrangements that will be in place ensuring access to data and to ensure the maintenance of high data quality from the new AF (i.e., arrangements that ensure that all data quality targets can be achieved and data quality guidelines can be adhered to).
- Discuss the impact of adding the AF on the Center's participation in the NDB (e.g., number of additional eligible NDB participants, additional data points).

2) If the NIDILRR Project Officer approves the addition of the AF, the Center must continue to pay close attention to all data quality targets to assure no reduction in data quality as a result of adding the new AF. The Center must continue to abide by SOP 606 "Performance Target Monitoring", which states that if any "in year" performance target is not met for two consecutive quarters, the TBIMS Project Director in consultation with TBIMS Center staff must provide an action plan to their NIDILRR Project Officer.

Training requirements:

None

Compliance:

All TBIMS Centers are responsible for complying with this policy and its procedures.

References:

None

History:

Date	Action
12/1/2016	SOP Created and Approved by Project Directors
6/1/2023	Revised language to match SOP DA001

Review schedule:

At least every 5 years.

OP008 Module Project Peer Review Procedures	
Review Committee: Research	Effective Date: 2/08/2010
Attachments: Module Project Template for Peer Review	Revised Date: 06/12/2015
Forms: Review Form	Reviewed Date: 12/07/2019

Introduction:

Module projects developed during a grant cycle do not receive external peer review, and therefore the proposers do not have the benefit of a critique by an outsider who has no vested interest in the project. This holds true both for modules developed at the very start of a new grant funding cycle and for ideas for research put forward at a later stage. The following peer review procedures adopted by the TBIMS aim to fill that gap by providing a peer review by experts from within the TBIMS, supplemented as needed/as possible by outside experts. The purpose of the review is to improve the quality of module research, and to optimize use of TBIMS resources.

Purpose:

To describe the process for initiating new module research projects and approving them through an internal peer review process.

Scope:

All TBIMS Centers and TBIMS Follow-up Centers, the NDSC, and NIDILRR.

Responsibilities:

The TBIMS, TBIMS Follow-up Centers, and NDSC will abide by this policy and procedure.

Procedural steps:

Please note that this SOP applies only to modules that have not already been peer reviewed as part of the TBIMS grant application process.

For **beginning-of-cycle modules**, the procedure is as follows. Because of the importance of starting up new projects as soon as possible after start of grant funding on October 1, timelines are indicated which are approximate, and do not take into account which dates fall on weekend days in what year:

1. By November 30: A one-page “concept paper” is distributed by all centers to all their colleagues using the Research Committee and Project Directors listservs.
2. December 15-16: At the Project Directors meeting, the originating center makes a brief presentation on their proposed project, after which there are meetings of all model systems who are interested in participating in each proposal.

3. December 16-January 1: For planning purposes, the Chair of the Research Committee creates a list of concept papers that are expected to evolve into formal proposals.
4. December 16-February 1: Based on further work and email/telephone discussion between interested centers, the originating center produces an 8-page proposal, following guidelines for proposal in the enclosed **TBI Model Systems Module Proposal Instructions**. The proposal should include a 'resource requirement' section, in which all expectations of each collaborating center (number of patients minimally required, by year of the module and/or year since injury; staff skills and staff hours [total and/or per patient] required, etc.), are specified, differentiated by number of participating centers. ("If two centers, each would need/contribute…; if three centers, …").
5. The proposals are routed to the Chair of the Research Committee, who assigns each proposal to a panel of at least three reviewers with expertise in the proposal's topic areas and/or research methodology/statistics. Reviewers should, if at all possible, work at centers which have not contributed to the proposal; at her/his discretion, and after consultation with the Research Committee membership as needed, the Chair may invite as panel members scholars from outside the model systems circle. A statistician employed by the TBI Model Systems National Data and Statistical Center is a member of each panel ex officio and without vote, unless the Chair of the Research Committee determines that there is no need for review by an expert statistician. Each panel has a Chair.
6. February 3-15: Panel members individually and independently complete the attached **TBI Model Systems Research Committee Peer Reviewer's Form** and send a copy to their fellow panelists. As per the Review Form, they rate each section on a 4-point scale, and give the overall proposal a global rating of 1 to 4, weighing the components as they see fit.
7. February 15-21: The panelists have a conference call to discuss the proposal, and may change their opinions and ratings based on the discussion. The teleconference is used to (a) resolve any major discrepancies between reviewers, (b) highlight the most important needs for revisions, if any, and (c) assign a final global score representing the consensus of the panel. The chair completes a form that has the key issues, especially a list of "fatal flaws" that the panelists could agree on. The Panel Chair distributes the reviews to all panel members prior to the teleconference. The teleconference is used to (a) resolve any major discrepancies between reviewers, (b) highlight the most important needs for revisions, if any, and (c) assign a final global score representing the consensus of the panel.
8. February 21-24: The panel members revise their individual rating forms (if they wish to do so) and send them to the panel chair.
9. February 25-27: The panel chair bundles the individual reviews and the panel discussion summary, and forwards them to the Research Committee chair. The Research Committee chair sends them to the originating model system with a request to modify their original proposal based on the feedback, or drop it if the participants agree with a judgment that there are fatal flaws, or that the proposal has limited scientific value (as expressed by a mean rater global score of less than 3.
10. March 1-30: The originating center and its collaborators work to revise the proposal in light of peer review comments.

11. April 1-30: Project directors and their staff review original proposals, peer reviews and revised proposals, and make decisions on which ones they will participate in the next few years. Decisions are communicated using the Project Directors list serve, so that all involved know who will be collaborating on what.
12. May 1-31: Project directors discuss budgetary implications of their selection with their project officer.
13. June15-16: First module implementation meeting held during the Project Directors meeting

For **modules first proposed during a cycle**, the procedure is as follows:

1. A proposal for a multi-center module project emerges from collaborators in at least 2 centers, preferably but not necessarily from a Special Interest Group (SIG).
2. The idea for the project is sent in draft form via the Notification process used for database projects, with the expectation that every effort will be made to incorporate all centers expressing an interest in collaboration. The NIDILRR Project Officer for each of the participating sites must approve the site's participation in the module.
3. The proposal is written using the **TBI Model Systems Module Proposal Instructions** (attached) and submitted to the Chair of the Research Committee (RC).
4. The Chair of the RC assigns an RC member to organize a Peer Review Panel. The Panel consists of three reviewers with expertise in the proposal's topic areas and/or research methodology/statistics. These reviewers should not have contributed to the proposal. If insufficient expertise is available within the TBIMS, outside experts may be invited. The assigned RC member will serve as Panel Chair, but need not be one of the reviewers.
5. Coordinated by the Panel Chair, panel members independently review the proposal and complete the **TBI Model Systems Research Committee Peer Reviewer's Form** (attached). As per the Review Form, they rate each section on a 4-point scale, and give the overall proposal a global rating of 1 to 4, weighing the components as they see fit.
6. Panel Reviews must be returned to the Panel Chair within 15 business days (3 weeks) of receipt. A 30-minute teleconference is pre-scheduled for the Review Panel for the week following this deadline.
7. The Panel Chair distributes the reviews to all panel members prior to the teleconference. The teleconference is used to (a) resolve any major discrepancies between reviewers, (b) highlight the most important needs for revisions, if any, and (c) assign a final global score representing the consensus of the panel.
8. The Panel Chair forwards the reviews, with scores and suggested revisions to the RC Chair, the SIG members who collaborated on the proposal, the NIDILRR TBIMS Program Manager and the NIDILRR Project Officers of the proposing Centers.
9. At the SIG's/originating group's request, the Panel Chair meets by telephone with the PI to answer questions on the review, and supply additional detail. Other Review Panel members and SIG/group members may join this discussion.
10. The entire process from submission of a proposal to the Research Committee Chair to receipt of a written review by proposer(s) will under normal circumstances take no longer than 2 months.
11. A global score of 3 or 4 indicates that the project may move forward. The proposal, the reviews with any recommendations for change, and the scores will be forwarded to the SIG members who collaborated on the proposal, the NIDILRR TBIMS Project Manager,

and the NIDILRR Project Officers of the proposing Centers, with an indication that the project may proceed. A notification of the approved project will also be sent to the PD list server, so that all centers may be informed of the new module projects.

12. A score of 1 or 2 reflects a judgment by the review panel that the project as proposed should not go forward. The originators of the proposal may revise and resubmit the proposal to the review panel once. If the score does not exceed 2 on the second try, the review process ends for that project. However, an appeal may be made to the Research Committee if the decision is perceived as inaccurate or unfair. The Research Committee will convene via teleconference call as needed and consider appeals on a case-by-case basis.
13. Once a project has been recommended and officially approved by NIDILRR, the assignment of a Project Officer, if necessary, will follow within 1-2 weeks.

Compliance:

All TBIMS Centers and TBIMS Follow-up Centers are responsible for adhering to this policy and its procedures.

References:

None

History:

Date	Action
7/1/2005	Version of procedure used to create this SOP
1/25/2010	Transferred to SOP template and revised
2/8/2010	Approved by Project Directors
2/16/2010	Added Submission Form and Reviewer Form
7/7/2014	Added start-of-cycle process and otherwise revised
6/12/2015	Updated NIDRR to NIDILRR
127/2019	Reviewed

Review schedule:

At least every 5 years.

TBI Model Systems Module Proposal Instructions

Please create a document for the proposed module project with each of the categories below. The length of the completed form should be about 8 pages (start-of-cycle proposal) or 3-5 pages (midcycle proposal) (single spaced). It is not necessary to include formatted references. Please note that this is a minimum length. If you have a longer proposal written for another purpose, e.g., IRB submission, information from it may be included without editing.

Title of project:

PI and lead center:

(Anticipated) Collaborators and their centers:

Period during which proposed project will collect data:

Start date:

End date:

Date this form is submitted:

Background and Significance **(knowledge gaps the research is intended to fill; innovative aspects of the research plan):**

Research Plan **(overview of experimental design, independent and dependent variables, specific aims, hypotheses):**

Methods **(participants: inclusion/ exclusion and anticipated number [power calculations]; procedure and instruments to be used in data collection [attach data collection forms if available]):**

Data Analysis Plan **(statistical methods to be used):**

Anticipated Outcome(s):

Resources expected to be contributed by a collaborating site. **(Describe both one-time, repeated and per-subject resources, in terms of required FTE/hours by category of staff, or dollars; differentiate various scenarios based on different numbers of participating sites):**

TBI Model System Research Committee Peer Reviewer's Form

Please create a document that details your critique of the proposal that has been submitted. Then submit your document to the Panel Chair and fellow panel members.

Title of project:

PI to whom feedback will be given:

Panel chair:

Reviewer:

Date of review:

Please rate on a scale from 1(poor) - 4(excellent), **and** provide comments on each of the following sections. List separately any flaws in the proposal that you consider to be fatal because of issues of cost, ethics, required number of subjects, nature of or quantity of steps in the protocol, or any other aspect of the research that you think cannot ever be fixed in a protocol revision. If there are no problems that doom the project in that way, write "no fatal flaws". Finally, submit a global score with the same scale with 1-2 indicating that in your opinion the proposal should not move forward, and 3-4 indicating approval of the proposal.

Background and Significance **(importance of knowledge gaps the research is intended to fill; innovative aspects of the research plan, etc.):**

Research Plan **(comments on experimental design, selection of independent and dependent variables, time points/periods for interventions/data collection, specific aims, hypotheses):**

Methods **(participants: inclusion/ exclusion and anticipated number [power calculations]; procedure and instruments to be used in data collection):**

Data Analysis Plan **(statistical methods to be used):**

Anticipated Outcome(s) **(useability/ transferability of anticipated findings to practice/research/other expected applications):**

Fatal flaws:

Comments, if any, on proposer's estimate of resources needed:

Background & Significance	1 2 3 4
Research Plan	1 2 3 4
Methods	1 2 3 4
Data Analysis Plan	1 2 3 4
Anticipated Outcomes	1 2 3 4
Global Rating	1 2 3 4