



107a Data Quality Guidelines and Principal Investigator Verification of Compliance	
Approved: TBIMS Project Directors	Effective Date: 7/1/2009
Attachments: None	Revised Date: 10/1/2009
Forms: PI Verification of Compliance with Data Quality Guidelines	Reviewed Date: 12/12/2008
Review Committee	SOP Committee

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. Functional Independence Measure (FIM):** FIM training will follow guidelines established as appropriate at each center (e.g, UDS, e-Rehab, etc.). It is the responsibility of each center to assure that all staff who perform FIM assessments and those performing the data quality checks (Form I and Form II) 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.
- 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 (Form I and Form II) are trained and certified through the website at "www.tbims.org/combi/drs". All staff should be re-certified bi-annually. The Northern



Traumatic Brain Injury Model Systems National Data and Statistical Center

STANDARDIZED OPERATING PROCEDURE 107a

California TBIMS (at Santa Clara Valley Medical Center) will send a reminder to individuals nearing the end of their two-year DRS credentialing.

3. **Premorbid History Data:** The Premorbid History Questionnaire should be used as a face-to-face interview, telephone interview, or mail-out survey to collect relevant data for the TBIMS National Database Form I. Exact wording of questions is provided. A patient version and a family version are found in the Database Syllabus. 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 TBIMS at the Santa Clara Valley Medical Center. The Database Syllabus contains the CT data collection form with guidelines.
5. **Data Collected From Medical Charts:** Each center will have an independent certified staff member re-abstract the entire Form I 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 report deadlines (e.g., March 31, June 30, September 30, December 31).
6. **Form I Certification:** Each center will have the staff responsible for completion of the Form I data collection for the TBIMS National Database complete the Form I 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. **Data Collection Forms:** Prior to data entry, a random sample of at least 10% of the Form I and Form II data collection forms will be reviewed by a different staff member for coding consistency. If any errors are found they should be corrected and another 10% of the forms should be reviewed. This should be done prior to the quarterly report deadlines.
8. **Data Entry:** Data entry for a random sample of at least 10% of Form I's and Form II's 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 report deadline.
9. **Correction of Data Errors:** All data errors identified by the NDSC or the individual centers will be investigated and corrected by each center prior to each quarterly report deadline.
10. **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.



Traumatic Brain Injury Model Systems National Data and Statistical Center

STANDARDIZED OPERATING PROCEDURE 107a

11. **Consistency of Data Collected by Interview:** Each center, on an annual basis, should have another center staff person sit in and code a Form II (via phone, recording, or in-person) on interviews for Form II data collection. If any errors are found they should be corrected and another interview should be coded by the independent staff person.
12. **Error Reports:** Each center should run the database error report after all data entry is completed for a quarterly report deadline and attempt to correct all errors before that quarterly deadline.
13. **Missing Data Reports:** Each center should run the database missing data report for Form I and Form II after all data entry is completed for a quarterly report deadline and attempt to complete all missing data before the quarterly deadline.
14. **Enrollment Report:** Each center should complete the database enrollment and be sure there are no error messages appearing prior to each quarterly report deadline.
15. **Form II's Overdue:** Each center should run the database Form II cases past due report after all data entry is completed for a quarterly report deadline and complete a Form II for any cases appearing on the list as past due. If no information is available on the participant, complete the Form II considering the participant as lost to follow-up. If any Form IIs are overdue for any quarterly report deadline, they will be considered lost to follow-up in the calculation of follow-up rates for the data quality targets.
16. **Quarterly Report:** Each center should run the database quarterly report after all data entry is completed for a quarterly report deadline and assure that all figures in the quarterly report match their data as this quarterly report will match the all centers quarterly report produced by the NDSC.
17. **Best Practices for Follow-up:** Each center should complete the Guidelines and Strategies for Maximizing Follow-up Form 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.
18. **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 II 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 II year 5,10, 15, etc. follow-ups each quarter and year; 5) maintain less than 10% missing data on all Form I and Form II variables each year.



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:

- 1) Completely revised version from data committee used to create this SOP = draft 10/28/2008 approved by Data Committee
- 2) Transferred to SOP template = 11/1/08
- 3) Approved by SOP Review Committee = 11/17/2008
- 4) Approved by Planning Committee and Project Directors 12/12/2008
- 5) Clarified what is considered "lost" for #17 7/1/2009
- 6) Clarified that a person conducting the re-abstraction should be certified. 10/1/2009
- 7) Change re-abstraction rate from 10% to just one 10/1/2009

Review schedule: At least every 5 years.