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:** FIM® training will follow guidelines established as appropriate at each center (e.g., UDS, e-Rehab, ITHealthTrack, 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 for Form I 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 Interview or Questionnaire should be used to collect relevant data for the TBIMS National Database Form I. 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.

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 NDSC (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 I on one of the cases 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 deadline (e.g., March 31, June 30, September 30, and January 15).

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. **Cultural Certification**: It is the responsibility of each center to assure that all staff responsible for enrollment, Form I Pre-Injury History collection or Form II 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 Is 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. The same procedure will be used for Form II 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 II for each Form II data collector. If any errors are found they should be corrected and another interview should be coded by the independent staff person.

11. **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. 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 is completed for a quarterly report 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 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 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.

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. **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.

These procedures are being followed in my TBI Model System.

____________________________________________
Signature of Project Director                                                                  Date

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Center Name