

**Burn Model System
National Data and Statistical Center**

STANDARD OPERATING PROCEDURE (SOP) #104

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| SOP #104 | Title: Data Quality Guidelines and Principal Investigator Verification of Compliance | |
| Approved: BMS Project Directors | | Effective Date: 4/29/2014 |
| Attachments: PI Verification of Compliance with Data Quality Guidelines | | Revised Date: 4/14/2016 |
| Forms: PI Verification of Compliance with Data Quality Guidelines | | Review Date: |
| Review Committee: BMS Project Directors | | |

Purpose:

Institute standardized practices for data quality in order to ensure data integrity.

Scope:

All Burn Model System (BMS) Centers and BMS longitudinal follow-up Centers that participate in data collection for the BMS National Database (NDB).

Responsibilities:

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1. **For implementation:** BMS staff responsible for data entered into the NDB (e.g., BMS researchers or clinicians, research assistants, and study coordinators).
 2. **For oversight:** Directors of BMS Centers and staff from the Burn National Data and Statistical Center (NDSC).

Procedural Steps:

Ongoing Procedures

1. **Patient Status Form:** The Patient Status Form will be completed for all patients who meet the eligibility criteria¹, including those who do not consent or choose not to participate for any reason. This form serves as the “cover sheet” for each eligible patient and, for patients who consent and become participants, includes PHI such as birth date and burn date. The Patient Status Form will be updated at follow-ups with information on return to work date or death date. The Form includes instructions about what information should be collected on those eligible patients who do not consent.
2. **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. The NDSC will correct the errors if possible and notify the other clinical centers that the error was found and what steps were taken to correct it.
3. **Best Practices for Follow-up:** Each Center will complete the Guidelines and Strategies for Maximizing Follow-up Form in the database for every participant

¹ Eligibility criteria is set forth in BMS SOP #101, Identification of Subjects

who 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 followed. Prior to assigning the status 'lost to follow-up' to a participant, the center will carry out all the guidelines and strategies on this participant as specified in the 'Guidelines and Strategies for Maximizing Follow-up Form' and then fill out and submit the form.

Quarterly Procedures

1. **Data Entry:** At the end of each quarter, data entry for a random sample of at least 10% of total Form Is and Form IIs entered will be verified by having a second staff member compare the complete data collection form to the data entered into the database. At the end of the quarter, the NDSC will provide each Center a list of the participant ID numbers whose data in the online data entry system should be verified. If any errors are detected, another 10% of total Form Is and IIs will be verified (the list of participant ID numbers will be generated by the NDSC). If there are any errors in this second verification process, all records entered for that quarter will be checked. This must be completed prior to each quarterly report deadline, and will be initiated by the NDSC.
2. **Missing Data Reports:** At the end of each quarter, the NDSC will run the database missing data report for Form I and Form II after all data entry is completed for a quarterly report deadline. Once reports are distributed, Centers will attempt to complete all missing data before the next quarterly deadline.
3. **Enrollment Report:** At the end of each quarter, BMS Centers will complete the subject enrollment data entry prior to each quarterly report deadline.
4. **Quarterly Report:** At the end of each quarter, the NDSC will run the database quarterly report after all data entry is completed for a quarterly report deadline. Once reports are distributed, Centers will assure that all figures in the NDSC quarterly report match their individual center tracking data as this quarterly report must match the "all centers" quarterly report produced by the NDSC.

Annual Procedures

1. **Data Collected by Medical Record:** At the end of each year, BMS Centers will have an additional Center staff person (independent from the original coder) double code the medical record abstraction data from five randomly selected discharge records. These records will be randomly selected by the NDSC. Double coding is defined as recoding the data from the medical record without referencing the original form filled out and entered for the BMS database. The data collector doing the double coding will fill out a blank medical record abstraction form from the medical record and then enter that data into REDCap using the same procedures as the double data entry process to determine if there are any discrepancies between the two coded abstractions.
2. Additionally, the variables for TBSA burn and graft, number of ventilator days and number of operations will be examined for five additional randomly selected participants who have a TBSA of 20% or higher. These five records will be randomly selected by the NDSC. A staff member independent from the original coder will compare the data in the medical record for the variables with the data

entered in REDCap and correct the data in REDCap if necessary. If discrepancies between the medical record and the BMS data entered into REDCap for these variables are found, the same variables on five additional records should be coded by the same or another independent staff person.

3. **Guidelines Sign-off by Project Directors:** At the end of each year, BMS Center Project Directors will submit a signed copy of this SOP to the NDSC, to indicate that these guidelines are being followed within their center. All signed guidelines will be archived by the NDSC.

Training requirements:

None

Compliance:

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

References:

None

History:

4/14/16: Revisions made to yearly data quality procedures to make them more relevant to BMS centers.

Review Schedule

At least every 5 years.

Signature of PI

Date