

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

**STANDARD OPERATING PROCEDURE (SOP) #105**

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| <b>SOP #105</b>                                | <b>Title:</b> Guidelines for Collection of Follow-up Data |  |
| <b>Approved:</b> BMS Project Directors         | <b>Effective Date:</b> 12/15/2014                         |  |
| <b>Attachments:</b> None                       | <b>Revised Date:</b> 12/21/2015                           |  |
| <b>Forms:</b> None                             | <b>Review Date:</b>                                       |  |
| <b>Review Committee:</b> BMS Project Directors |   |  |

**Introduction:**

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The Burn Model System (BMS) uses an established set of rules including procedural steps for follow-up data collection (FORM II) for the BMS National Database (NDB).

**Purpose:**

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

**Scope:**

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

**Responsibilities:**

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

**Guidelines:**

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Data Collection Windows

1. For the six month follow-up, data collection should occur within a window of 2 months before to 2 months after the 6-month anniversary date of the injury, based on a standardized 30 day month (ie, 2 months is equal to 60 days)
2. For the one year follow-up, data collection should occur within a window of 3 months before to 3 months after the 1-year anniversary date of the injury, based on a standardized 30 day month (ie, 3 months is equal to 90 days).
3. For the two year follow-up, data collection should occur within a window of 6 months before to 6 months after the 2-year anniversary date of the injury, based on a standardized 30 day month (ie, 6 months is equal to 180 days).
4. For follow-up years 5, 10, 15, etc., data collection should occur within a window of 12 months before to 12 months after every 5, 10, 15, etc. -year anniversary date of the injury, with 12 months being defined as one calendar year, with the window opening and closing on the identical date as the anniversary date in the previous and following years.

### Handling Events at Follow-up:

1. Follow-up should be attempted according to the BMS schedule for every participant for whom a Form I was submitted, unless the participant was reported as expired or withdrew authorization to collect data in a prior follow-up period.
2. If a participant expires during initial acute care, no Form II is to be completed.
3. DECEASED or WITHDREW AUTHORIZATION. For participants who have died or who withdrew authorization to continue with the study, enter the follow-up status in the appropriate time-point. If the data collector learns prior to window opening that the person expired or withdrew 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. For expired participants and those who withdrew authorization, no additional Form II's are ever entered.
  - i. 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.
  - ii. If a participant **withdraws authorization** and then changes their mind and **decides to enter the study again**, that participant should be consented to the study following consenting procedures.
4. INCARCERATED. Data should not be collected from the participant 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 II 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. 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, BMS centers should check with their individual IRB and review OHRP guidelines (US Dept of Health & Human Services Office for Human Research Protections.)

5. If a participant is still in the hospital at the time that their follow-up window closes, fill out the follow-up status with “patient still in hospital”. This follow-up status will not be counted against centers in the quarterly follow-up report
6. If a participant was discharged from the hospital during their six month or 1 –year window, the six month or 1-year follow-up data should still be collected (or attempted to be collected) during the window. Data collectors should attempt to collect the follow-up data as late as possible after the discharge data was collected but still during the window.
7. A participant may refuse to be interviewed in a given year because they are too busy or do not wish to be bothered, etc. If this is the case, the interviewer should ask if he/she can contact the participant at the next follow-up window. If the participant agrees, then they are considered to have “**refused**” the current follow- up interview but not to have withdrawn authorization, and contact should be attempted at the next follow-up window.

#### Follow-up Data Collection Procedures:

1. The primary source of information for the annual follow-up should be the participant or the appropriate parent proxy for pediatric participants.
2. Questions that the parent proxy cannot answer reliably are coded as “unknown”.
3. 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. For all datasets, a calculated variable will be provided that indicates the length of days outside the follow-up window so analysts can determine what to do with this data for the purposes of their project.
4. 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 II’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.
5. If telephone contact with the participant and significant others is unsuccessful, the participant should be sent the mail version of the Form II after personalized information (name, enrollment date,

name and contact information of Form II data collector) has been added to the form, along with a self- addressed return envelope.

**Training requirements:**

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

**Compliance:**

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All follow-up data collectors are required to comply with these guidelines.

**References:**

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None

**History:**

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12/21/2015: Edited to clarify definitions of window time periods.

**Review schedule:**

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At least every 5 years.