

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

STANDARD OPERATING PROCEDURE (SOP) #605

SOP #605	Title: Creating and Changing Standard Operating Procedures SOP and Form	
Approved: BMS Project Directors		Effective Date: 4/24/2012
Attachments: SOP Template Form		Revised Date: 9/30/2015
Forms: SOP Template Form		Review Date:
Review Committee: BMS Project Directors		

Introduction:

This Standard Operating Procedure (SOP) addresses the need for a formal systematic approach for creating and documenting the policies and practices of the Burn Injury Model System (BMS) Centers Program. SOPs on specific topics such as requesting the BMS National Database are intended to assist in defining, systematizing, and formalizing the policies and procedures of the BMS Centers, including, but not limited to, the activities associated with the BMS National Database. SOPs must be developed, changed, and finalized using the specific procedural steps outlined below. Project Directors (PDs) refers to the Project Directors of the NIDILRR-funded BMS Center grants.

Purpose:

To define a structured process by which SOPs are developed or changed for implementation.

Scope:

BMS Centers and the BMS National Data and Statistical Center (NDSC).

Responsibilities:

All BMS Centers and the BMS NDSC must abide by this procedure.

Policy:

Development, revision and approval of SOPs are the primary responsibility of the BMS PDs, in consultation with the BMS NDSC. NIDILRR provides input and guidance to the SOP development, revision and approval process. This input may include but is not limited to the sharing of previous experiences and expertise, clarification or interpretation of the original intent of the published Priority, and recommendations that aim to improve collaborations between BMS Centers and across the three NIDILRR-funded Model System Center Programs. Approved SOPs will be made available to the BMS Centers and to the public by the BMS NDSC to promote compliance with, accountability for, and transparency of policies and practices.

Procedures:

I. Developing a new SOP:

- A. The NDSC coordinates the administrative aspects of the SOP development process.
- B. A new SOP must originate from either the NDSC or a BMS Center which will complete the SOP template (attached).
 1. The draft SOP is sent by the originator to the NDSC and to the NIDILRR BMS Program Manager for review.
 2. The NDSC and the NIDILRR Program Manager provide feedback and/or edits to the originator. All edits and contextual changes will be taken into consideration during this stage and tracked using MS Word Track Changes.
 3. The NDSC posts the (revised) draft SOP to the BMS listserv for comment by the PDs (and by additional BMS staff if desired). A deadline date for the comment period (typically 10-14 days from the date of posting) is provided by the NDSC.
 4. If a PD has a concern about the draft SOP, he/she should express that concern during the comment period and edit the document using MS Word Track Changes to address/resolve the concern. Editing the SOP to address the concern is the primary responsibility of the PD who raises the concern although others may provide additional suggestions for edits to address the same concern. PDs should send comments and the edited SOP document to the BMS listserv as early as possible during the comment period to allow others to respond in kind before the deadline. PDs should review the SOP in light of the explicit purpose (see "Purpose" section) of the SOP. It is important that each SOP has a legitimate purpose and the policies and procedures adequately address the original concerns or need.
 5. PDs should comment on the edits made by other Project Directors if such edits raise concern. As in 4, above, such a comment should be accompanied by edits to the SOP, if applicable. The comment and revised SOP should be posted to the listserv within the comment period.
 6. The NDSC will compile and reconcile comments, recommendations and all inconsistencies that are identified during the comment period and then produce a final draft for approval by the PDs.
 7. PDs should review the final draft SOP in a timely manner, and submit one vote per center during the "voting period", established by the NDSC (typically 10 days from the date of posting).
 - i. All comments and votes should be sent to the listserv, not to the NDSC. After the designated voting period is closed, non-response by a BMS Center will be considered an affirmative response. A majority vote of the BMS PDs is required to approve new or revised SOPs. In the event of a tie, discussion will continue until a majority vote is achieved.

- ii. After approval, the SOP goes into effect on the effective date displayed in the SOP header and is posted to the NDSC website.

C. The SOP will be reviewed according to the schedule specified in the SOP.

II. Making changes to Existing SOPs:

- A. The NDSC coordinates the administrative aspects of the SOP revision process.
- B. Proposals for revisions to an existing SOP may be raised by the NDSC or a BSMS Center which will revise the SOP and send to the NDSC and to the NIDILRR BMS Program Manager for review. The structure of the BMS SOP template (attached) should be maintained.
- C. The draft revised SOP together with a short paragraph outlining the changes to the SOP is sent by the originator to the NDSC and to the NIDILRR BMS Program Manager for review.
- D. The NDSC and the NIDILRR Program Manager provide feedback and/or edits to the originator. All edits and contextual changes will be taken into consideration during this stage and tracked using MS Word Track Changes.
- E. The steps outlined above (in I B.3-B.7) follow.

Training requirements:

None

Compliance:

Staff of the BMS Centers and of the NDSC must comply with this SOP.

References:

None

History:

4/24/12—Approved

9/30/15—Updated to replace all references to NIDRR with NIDILRR.

Review schedule:

Review at least every 5 years.

**Burn Model System
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STANDARD OPERATING PROCEDURE (SOP) #605 FORM: SOP Template**

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STANDARDIZED OPERATING PROCEDURE #

SOP #	Title:		
Approved:		Effective Date:	
Attachments:		Revised Date:	
Forms:		Review Date:	
Review Committee:			

Introduction:

Purpose:

Scope:

Responsibilities:

Policy:

Procedures:

Training requirements:

Compliance:

References:

History:

Review schedule:
