

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

**STANDARD OPERATING PROCEDURE (SOP) #602**

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| <b>SOP #602</b>  | <b>Title:</b> Internal Notification for Research using BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets SOP and Forms |                                  |
| <b>Approved:</b> BMS Centers Project Directors   |   | <b>Effective Date:</b> 4/24/2012 |
| <b>Attachments:</b> Internal Notification for Research using BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets SOP #602 Form A; Request for the Entire Dataset from the National Database SOP #602 Form B; Internal Notification for Additional Research using Previously Approved BMS Dataset SOP #602 Form C.                   |   | <b>Revised Date:</b> 6/22/2022   |
| <b>Forms:</b> Internal Notification for Research using BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets SOP #602 Form A; Request for the Entire dataset from the National Database SOP #602 Form B; Internal Notification for Additional Research using Previously Approved BMS Dataset SOP #602 Form C; NDSC Data Use Agreement |   | <b>Review Date:</b>              |
| <b>Review Committee:</b> BMS Project Directors   |   |                                  |

**Introduction:**

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This policy and procedure addresses the use of data from the multi-center Burn Model System (BMS) National Database, Archived Collaborative Study Datasets and Ongoing Collaborative Study Datasets by internal BMS users (i.e., by investigators or grant staff of the BMS Centers and BMS Longitudinal Follow-Up Centers).

**Note:** Upon the introduction of the BMS Standard Operating Procedure #608: Branding and Authorship Policy, guidelines for authorship and branding appear in that SOP and must be followed in all internal requests carried out according to this SOP.

This SOP outlines **two forms** of internal requests: that of a subset of data for a specific research question, and a request for all data in the entire National Database. Instructions for accessing a *subset of the data with a specific research question are outlined below, in Procedures Section I.-X.* Instructions for *accessing all data in the National Database are outlined in Procedures Section XI.*

**Purpose:**

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To define the process by which BMS Centers, the BMS National Data and Statistical Center, and BMS Longitudinal Follow-Up Centers (collectively referred to as “CENTERS” throughout this document) may use the data from the BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets for publication and presentation, including the notification process to be used to inform others of one’s plan and progress.

- I. To establish procedures for assuring productive and efficient research activities using the multi-center BMS National Database, Archived, Collaborative Study Datasets, and Ongoing Collaborative Study Datasets.
- II. To enhance the awareness of those associated with the CENTERS of pending and ongoing research studies that use the BMS National Database data, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets from study inception through publication of study findings.
- III. To encourage and assure the appropriate level of participation by all BMS clinical center staff on projects that utilize the BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets.
- IV. To establish procedures for multiple project/abstracts/manuscripts resulting from one dataset.

**Scope:**

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Staff of the BMS Centers: All staff, students, and other related personnel currently funded in the NIDILRR BMS Centers and the BMS National Data and Statistical Center who wish to use data from the BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets.

**Note:** This SOP does not apply to public users (i.e., external requests to utilize data of the BMS National Database). For public users and external requests, see SOP #604, *External Request for BMS Database*.

**Responsibilities:**

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All CENTERS, and the BMS National Data and Statistical Center (NDSC) will abide by this procedure. Additional responsibilities are outlined in the steps below.

**Policy:**

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The BMS Centers are committed to using and encouraging the use of the BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets in a time-efficient and effective manner to answer appropriate research questions. These policies and procedures were designed to guide the BMS grantees’ use of the data from the BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets by the Centers.

- I. An analysis plan may be proposed by one or more CENTERS or the NDSC. All CENTERS and the NDSC must be notified of the proposed analysis and offered the opportunity to participate in the research project. The procedure detailed below is designed primarily for notification purposes and to allow other CENTERS to collaborate if desired or needed.
- II. If an investigator on a proposed or existing project becomes unaffiliated with a BMS CENTER, he or she may continue involvement in the project, at the discretion of the Project Director(s) of the lead CENTER, and assuming sufficient funding and resources are available to complete the project.
- III. If a center's grant funding ends after the internal notification process has begun, but before the proposed study is completed, the center may continue their involvement in the study.
- IV. If a center no longer has BMS grant funding and has not become a BMS Longitudinal Follow-up Center, but wishes to propose a new study using the BMS national database, the processes outlined in the "SOP #604 External Request for BMS National Database and Archived Collaborative Study Datasets SOP and Form" should be followed.
- V. If the lead CENTER decides to generate more than one project/abstract/manuscript using the same dataset, another notification for the additional project/abstract/manuscript should be sent to the BMS Listserv inviting co-authors for the additional project/abstract/manuscript(s).

### **Procedure:**

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#### **I. *Notification Process:***

- A. The Lead Investigator for the proposed project, with the approval of the site's PD, will send an email notification of the proposed project to the BMS Listserv. The email should include a completed "Internal Notification for Research Using Data from the BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets SOP #602 Form A" (Form included at the end of this SOP) that summarizes the details of the proposed project. This form identifies the staff member who will serve as the PI of the proposed study. The PI of the proposed study may be, but is not required to be, the PD of the CENTER. The form also identifies who will be carrying out the proposed analyses (ie, BMS Center staff OR BMS NDSC staff).
- B. The email notification about the proposed project should occur as early as possible in the research process in order to most efficiently facilitate involvement by interested collaborators and to allow for a check for duplication of projects. Ideally, the notification will occur at the time of the initial planning process when an idea and methodology are being generated and before actual analyses are performed.
- C. An exception to (I.B.) above is the deadline for internal notifications prior to the American Burn Association (ABA) abstract due date. All internal notifications for projects that the lead investigator plans to submit to the ABA must be sent to the listserv 2 months prior to the ABA abstract due date. This timeline allows for: (a)

discussion of all internal notifications of proposed projects to be submitted to the ABA) during a monthly BMS Project Directors teleconference, and (b) all abstracts to be finalized with approval from all co-authors before the abstracts are submitted to the ABA for consideration. The NDSC will notify the listserv of the deadline for internal notifications for ABA submission 1 month before such notifications are due.

- D. If the lead CENTER wants to develop an additional project/abstract/manuscript based on an original dataset requested and approved using “Internal Notification for Research Using Data from the BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets SOP #602 Form A”, the lead CENTER will complete “Internal Notification for Additional Research using Previously Requested BMS National Database, Archived Collaborative Datasets, and Ongoing Collaborative Datasets Form SOP #602 Form C” to ensure that all BMS stakeholders are aware of projects/abstracts/manuscripts developed using BMS data and have the opportunity to participate in the additional projects/abstracts/manuscripts. The subject line on the notification to the listserv should clearly state that the request is a resubmission of a previously approved project/abstract/manuscript (including the title and date of the previously approved project/abstract/manuscript).

## **II. *Collaboration:***

- A. Staff from other CENTERS that are interested in collaborating on the proposed project have 10 working days from the date of notification in which to contact the lead investigator via email to express the desire to collaborate. Those wishing to participate will describe meaningful input they could offer to the project. The lead investigator for the proposed project retains the right to accept or decline the participation of interested researchers based on her/his judgment as to whether the contributions will meet the needs of the project. There may be multiple authors from the proposing center and additional authors from collaborating CENTERS. It will be the responsibility of the lead investigator and the other interested parties to work out a satisfactory arrangement regarding authorship and responsibilities.
- B. If no CENTER responds to the proposed project notification by expressing interest within the 10-day notification period, it is permissible for the lead investigator to move forward with the project.
- C. Non-response by a CENTER within 10 working days from the date of the notification indicates that the lead investigator may proceed with the project without that CENTER’s participation, and that that the project does not duplicate a prior project.
- D. At the end of the 10-day notification period, the lead investigator must post an updated, “Internal Notification for Research using BMS National Database data, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets SOP #602 Form A” (that includes the updated list of collaborators) to the BMS listserv, including the names of all project participants.
- E. The lead investigator will then work with the BMS NDSC to create a dataset that includes the variables identified in the “Internal Notification for Research using BMS National Database data, Archived Collaborative Study Datasets, and

Ongoing Collaborative Study Datasets SOP #602 Form A" (Form Attached). Once created, the dataset is sent to the lead investigator or designee of the lead CENTER along with notifying the center's PD.

- F. When an additional project/abstract/manuscript is developed using a dataset already requested and approved, the lead CENTER will solicit collaboration on the new manuscript. Researchers who contributed to the initial project/abstract/manuscript do not need to participate in the additional project/abstract/manuscript, and researchers who did not participate in the first manuscript can choose to participate in the additional project/abstract/manuscript.

### **III. *Research Registry:***

- A. The BMS NDSC will maintain a list of projects submitted through the notification process and will post it on the BMS National Data and Statistical Center website (<http://burndata.washington.edu/publications-progress>). The BMS NDSC also makes the list available at the BMS Project Directors' meetings by adding it to the meeting agenda and meeting minutes.
- B. The lead investigator is responsible for updating the BMS NDSC regarding the status of the project. The NDSC solicits updates on a regular basis, which should be provided by the lead investigator.
- C. Any project that has been posted to the notification listserv but that has not proceeded into data analysis or presentation/abstract/manuscript drafting within 1 year after the initial notification period will be discussed by the PDs during a BMS meeting. Barriers to moving the project forward will be discussed, with an aim to provide any necessary support for the project to proceed. If significant progress has not been made on the project by the third year after the notification (significant progress meaning manuscript nearing completion and ready for submission), the project will be opened to other CENTER investigators who wish to develop and propose a study according to the procedures outlined in this SOP.
- D. The NDSC will add additional projects/abstracts/manuscripts utilizing already approved datasets and requested using SOP #602 Form C to the research registry. These will be added as subprojects of the original project that was requested and approved so that it is clear to all researchers which datasets are in use and involve more than one project/abstract/manuscript in development.

### **IV. *Duplicate or Overlapping Studies:***

If a project posted to the BMS listserv bears substantial resemblance to one that was previously posted, and/or published or presented, the lead investigator of the earlier project should notify the lead investigator posting the duplicate project. The two lead investigators should attempt to come to an agreement that avoids duplication of research. Such agreement may involve (a) the second lead investigator and/or collaborators joining as collaborators on the first study; (b) the aims and methods of one or both studies being changed to avoid duplication; or (c) the second study being discontinued as duplicative. The study first posted to the notification listserv will be given priority in this decision. The nature of the final agreement may depend on the status of each research project at the time

when the duplication is noted, and the specific interests of both lead investigators.

**V. *Objections:***

Objections to the use of National BMS Database data, Archived Collaborative Datasets, and Ongoing Collaborative Datasets as proposed in the notification should be sent by email to the originating lead investigator and the NDSC within 10 working days of the notification, including a rationale and constructive suggestions.

**VI. *Authorship:***

In addition to the above requirements, authorship of publications or presentations must follow guidelines set forth in **BMS Standard Operating Procedure #608:**

**Branding and Authorship Policy**, available here:

<http://burndata.washington.edu/standard-operating-procedures>. These follow the International Committee of Medical Journal Authors guidelines for authorship.

**VII. *Branding:***

Branding of publications or presentations must follow guidelines set forth in **BMS Standard Operating Procedure #608: Branding and Authorship Policy**.

**VIII. *Withdrawal and Resubmission:***

Authors of a publication or presentation that was submitted without fulfilling the requirements of Sections I-VI will be asked to withdraw the publication or presentation and resubmit after the requirements have been fulfilled. Sections I-V need only be accomplished once per project unless there is substantive change in project objectives or analysis. However, Section VI must be fulfilled for each publication/presentation derived from the project.

**IX. *Archived and Ongoing Collaborative Study Datasets:***

*Archived Collaborative Study Datasets* are the archived datasets resulting from time-limited research studies involving more than one BMS Center. They include but are not limited to collaborative module studies which generally start at the beginning of a BMS grant cycle and are intended to conclude prior to the end of the same grant funding cycle. Notifications of requests to use Archived Collaborative Study Datasets for anything other than the originally intended analyses should be submitted using the above described procedures.

*Ongoing Collaborative Study Datasets* are those datasets resulting from time-limited research studies involving more than one BMS Center, but that are not yet archived because data collection is ongoing. Requests to use Ongoing Collaborative Study Datasets for anything other than the originally intended analyses should be submitted using the above described procedures (I-VI). The participant BMS researchers in an ongoing collaborative study maintain the right to deny such a

request until such time as the dataset is archived or 2 years following the end of data collection, whichever comes first.

**X. *Grant-funded studies Using BMS Data:***

Project Directors may propose to use the BMS National Database, Archived Collaborative Study Datasets, and/or Ongoing Collaborative Study Datasets in studies for new, original applications under the NIDILRR BMS Centers Program. In this case, Project Directors are encouraged to follow the notification process before submission of the grant application, regardless of the number of centers involved. If duplicate studies are posted, resolution should be sought per the procedures discussed above.

If seeking funding from an agency or program other than the NIDILRR BMS Centers Program for a project that involves use of the BMS National Database, Archived Collaborative Study Datasets, and/or Ongoing Collaborative Study Datasets, the lead investigator is encouraged to follow the notification process before submission for such funding. However the detailed hypotheses and methods need not be disclosed.

**XI. *Request for Entire BMS National Database Dataset:***

The complete BMS National Database is available only to the BMS Project Directors, and such access does not require a research hypothesis or proposed project. To access any BMS data in the database, BMS Project Directors will use the following procedures:

- A. The BMS National Database containing all BMS data is updated in REDCap by the individual BMS Centers: as participants are enrolled and subsequently discharged from inpatient treatment for their burn injuries, and after collection of information at each follow-up event.
- B. The BMS Project Directors and Co-Directors are the only persons who may request complete data in the BMS National Database. BMS Project Co-Directors may request data only after prior written arrangements have been made between the Project Director and the BMS National Data and Statistical Center.
- C. The Project Director (or Co-Director) who receives all the data in the BMS National Database is permitted to release it to his/her BMS staff if such release is deemed necessary by the Project Director.
- D. To ensure the safety and integrity of the data as well as its proper use, the Project Director (or Co-Director) shall not release the BMS data to anyone other than those involved in his/her currently-funded BMS project, and will assume responsibility for ensuring that his/her staff does not release the data to unauthorized users.
- E. For dissemination of any information contained in the BMS National Database, refer to the procedures for authorship and publication, elsewhere in this SOP and the procedures for Branding, in **SOP #608 Branding and Authorship**.
- F. The form titled "Request for the complete data in the National Database SOP 602 Form B" must be completed and sent via email, fax or mail to the BMS National Data and Statistical Center.

- G. If a BMS Project Director wishes to receive a complete dataset from the BMS National Database that contains PHI, their center must have a fully executed Data Use Agreement on file with the National Data and Statistical Center. Otherwise, The National Database dataset to be made available will not contain Protected Health Information (PHI).
- H. The currently funded BMS National Data and Statistical Center will track requests for the data from the BMS National Database.

**XII. *Public Use:***

Refer to the #604, **BMS Standard Operating Procedure “External Request for Data,”** regarding external requests for the BMS National Database and for archived collaborative study datasets.

**Any author of a publication utilizing the BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets will produce the de-identified data on which the manuscript is based for examination, if requested by an editor, reviewer or reader of the publication. In such circumstances, review by the BMS National Data and Statistical Center will not be required before such data are released. However, the assistance of the NDSC can be requested in order to ensure the dataset is properly de-identified and ready to be shared with such an entity.**

**Training requirements:**

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None

**Compliance:**

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All BMS Center and NDSC users of the BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets must comply with this procedure.

**References:**

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None

**History:**

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2/24/12—This SOP replaces Policy 1998-02 (Disseminating multi-center data)

3/8/12—Revised

4/24/12—Approved

9/24/12—Revised

7/30/13—Revised to clarify that the NDSC uses the internal notification procedure to propose analyses of the BMS National Database.

2/3/14—Revised to add the discussion of the projects at the monthly teleconferences, branding of BMS publications, and to add ICMJE authorship guidelines.

4/14/14—Revised to clarify some wording issues and add specific ABA deadline.

3/12/15—Revised to reflect separate branding and authorship policy, SOP #608.

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



9/19/16—Revised to reflect discussion after year 1 if project has not proceeded and forfeit after year 3.

5/31/19—Revised to incorporate SOP #603, Request for National Database SOP into procedures and remove redundancies between the two procedures.

8/27/20—Revised to incorporate issues related to project resubmissions and duplicative/overlapping projects

11/29/21—Revised to incorporate information about who will be carrying out proposed analyses.

6/22/22—Revised to add GeoCodes and linking dataset information and to clarify that the NDSC will assist in preparing datasets for submission to publications when requested.

**Review schedule:**

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Review every year

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

**STANDARD OPERATING PROCEDURE (SOP) #602 FORM A.**  
Internal Notification for Research using BMS National Database, Archived  
Collaborative Datasets, and Ongoing Collaborative Datasets Form

*Note: This form is for use by BMS Model Systems Centers, the NDSC, and BMS Longitudinal Follow-Up Centers only.*

**Title of project:**

**Name of Principal Investigator of proposed study:**

**Name of lead CENTER:**

**Email address of Principal Investigator of proposed study:**

**Collaborators' names (after each name, please include the collaborator's affiliated center or organization in parentheses):**

**Notification date:**

**Start date for data inclusion:**

**Completion date: (actual or projected) for data inclusion:**

**Participants to be used:**

Include enrolled participants only, i.e., only those who were alive at discharge and who consented to participate.

Include everyone in the database.

**Dataset to be used (check all that apply):**

BMS National Database

Archived Collaborative Study Dataset (specify): \_\_\_\_\_

Ongoing Collaborative Study

Dataset (specify): \_\_\_\_\_

**Time-points to be included:**

Pre-burn  Discharge (d/c)  6-month post burn  12-month post burn

24-month post burn

5-year post burn  10-year post burn  15-year post burn

20-year post burn

**If requesting more than 1 time-point**, do you want data to be stacked (i.e., one record for each participant at each time-point, resulting in multiple rows of observations for each participant) or wide (i.e., only 1 record or one row per participant and all variables collected at more than one time-point re-name with var\_2 or var\_3 etc. for the different collection timepoints):

stacked/long  wide

**Entity carrying out proposed analyses:**

BMS Center staff  NDSC staff

Note: If NDSC is doing analyses, include an NDSC staff member on authorship list (NDSC staff member will follow ICMJE criteria for authorship, as defined by SOP #608, Branding and Authorship).

**Electronic data format desired:**

Excel  MS Access  SAS  STATA  SPSS   
Simple text file  
 Other: \_\_\_\_\_(pending acceptance by Data Center)

**Study sample:**

**Primary research hypotheses/aims:**

**Abstract (100 words or less):**

**Primary outcome measures:**

**Do you intend to link the BMS NDB with any other datasets?** If so, please describe the data to be linked to the BMS National Database or Archived or Ongoing Collaborative Database data (as defined in the SOP), and the linking procedures/techniques to be used:

a. Do you require any linking variables in the limited dataset? If so, please check those required and include justification of why variable is needed for the purposes of your study: \_\_

- \_\_ State Code
- \_\_ County Code
- \_\_ CensusTract
- \_\_ CensusBlock
- \_\_ Zip Code

**Research analysis (proposed):**

**Variables requested:**

**Calculated variables requested (e.g., time since injury, age at follow-up, time till**

**death, etc)**

**Name of Project Director of lead CENTER (Print):**

**Signature of Project Director of lead CENTER:**



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

**STANDARD OPERATING PROCEDURE (SOP) #602 FORM C.**

Internal Notification for Additional Research using Previously Approved BMS  
National Database, Archived Collaborative Datasets, and Ongoing Collaborative  
Datasets Form

*Note: This form is for use by BMS Model Systems Centers, the NDSC, and BMS Longitudinal Follow-Up Centers only.*

Title of initial project approved using SOP #602 Form A:

Title of new project:

Name of Principal Investigator of proposed study:

Name of lead CENTER:

Email address of Principal Investigator of proposed study:

Collaborators' names (after each name, please include the collaborator's affiliated center or organization in parentheses):

Notification date:

Completion date: (actual or projected) for data inclusion:

Primary *initial* research hypotheses/aims (from original SOP #602 Form A):

Primary new research hypotheses/aims:

Research analysis (proposed):

Entity carrying out proposed analyses:

BMS Center staff     NDSC staff

Name of Project Director of lead CENTER (Print):

Signature of Project Director of lead CENTER: