

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

STANDARD OPERATING PROCEDURE (SOP) #602

SOP #602	Title: Internal Notification for Research using BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative	
Approved: BMS Centers Project Directors		Effective Date: 4/24/2012
Attachments: Internal Notification for Research using BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets Form		Revised Date: 9/19/2016
Forms: Internal Notification for Research using BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets Form; NDSC Data Use Agreement		Review Date:
Review Committee: BMS Project Directors		

Introduction:

This policy and procedure addresses the use of 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 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.

Purpose:

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 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, 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 eligible staff on

projects that utilize the BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets.

Scope:

- I. Staff of the BMS Centers: All staff, students, and other related personnel involved in the NIDILRR-funded 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.
- II. Staff of previously funded BMS Centers that are, at the time of request, funded as BMS Longitudinal Follow-up Centers.

Note: This does not apply to public users (i.e., external requests to utilize data of the BMS National Database). Previously funded BMS Centers that are NOT current BMS Longitudinal Follow-up Centers must follow the external request process.

Responsibilities:

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:

The BMS Centers are committed to 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 use of the BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets by the Centers.

- I. An analysis may be proposed by one or more CENTERS or the NDSC, although all CENTERS and the NDSC must be notified and offered the opportunity to participate. 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 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 is defunded 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 defunded center that has become a BMS Longitudinal Follow-up Center wishes to propose a new study using the national database, the center may do so using the processes outlined in this SOP.
- V. If a defunded center 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 "External Request for BMS National Database and Archived Collaborative Study Datasets SOP and Form" should be followed.

Procedure:

I. *Notification Process:*

- A. The Investigator, with the approval of the site's PD, proposing the study should send an email notification of the proposed project to the BMS Listserv. The email should include a completed "Internal Notification for Research using BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets Form" (Form Attached) that summarizes the proposed project. This form identifies the staff member at the lead CENTER 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.
- B. The notification should occur as early as possible in the research process in order to facilitate involvement by interested collaborators and to allow for a check for duplication of projects. Ideally, this is 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 the above is the deadline for internal notifications prior to the American Burn Association (ABA) abstract deadline. 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 abstract deadline. This timeline allows: (a) for discussion of all internal notifications (that propose projects to be submitted to the ABA) during a monthly teleconference, and (b) for all abstracts to be finalized and submitted to 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.

II. *Collaboration:*

- A. Staff from other Centers that are interested in collaborating on the project have 10 working days from the date of notification in which to contact the PI via email and express the desire to collaborate. Those wishing to participate should suggest meaningful input they could offer to the project. The PI has the right to accept or decline the participation of interested researchers based on her/his judgment as to whether the contributions of each will meet the needs of the project. There may be multiple authors from the proposing center and others from collaborating BMS center(s). It will be the responsibility of the proposing center and the other interested parties to work out a satisfactory arrangement as to authorship and responsibilities.
- B. If no CENTER responds to the notification by expressing interest, it is permissible to move forward with the project after the 10-day notification period has ended.
- C. It is assumed that non-response by a CENTER within 10 working days from date of notification indicates that the project may proceed 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 PI must post an updated

- “Internal Notification for Research using BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets Form” (that includes the updated list of collaborators) to the BMS listserv.
- E. The PI then works with the BMS NDSC to identify a restricted dataset that includes the variables identified in the “Internal Notification for Research using BMS National Database, Archived Collaborative Study Datasets, and Ongoing Collaborative Study Datasets Form” (Form Attached). Once identified, the restricted dataset is sent to the Investigator or designee of the lead CENTER along with notifying the center’s PD.

III. *Research Registry:*

- A. The BMS NDSC will maintain a list of projects submitted through the notification process and will make it available on the BMS National Data and Statistical Center website (<http://burndata.washington.edu/current-projects>). The BMS NDSC will also make the list available as requested at the BMS Project Directors’ meetings.
- B. The PI is responsible for notifying the BMS National Data and Statistical Center of updates to the project. This should be done at the end of the 10-day notification period and then annually on the date of the initial notification, at a minimum.
- C. Any project that has been posted to the notification listserv but that has not proceeded into data analysis or presentation/abstract/manuscript drafting 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 support if needed 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 open to other investigators. The topic is then available to any researcher who wishes to develop and propose a study according to the procedures outlined in this SOP.

IV. *Duplicate Studies:*

If a project posted to the BMS listserv bears substantial resemblance to one that was previously posted and/or published or presented, the PI of the earlier project should notify the PI who has just posted the duplicate project. The two PIs should attempt to come to an agreement that avoids duplication of research. Such agreement may involve (a) the second PI 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 if both studies proceed; or (c) the second study being discontinued as duplicative. The study first posted to the notification listserv should be given priority in this decision. The nature of the agreement may depend on the status of each research project at the time when the duplication is noted, and the specific interests of both PIs.

V. *Objections:*

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

VI. Authorship

- A. 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. These follow the International Committee of Medical Journal Authors guidelines for authorship

VII. Branding

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

VIII. *Withdrawal and Resubmission*

- A. Authors of a publication or presentation that was submitted without fulfilling the requirements of Sections I-VI will be asked to withdraw the presentation or publication and resubmit after the requirements have been fulfilled. Sections I-V need only be accomplished once per project unless there is substantive change. 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 those archived datasets resulting from time limited research studies involving more than one BMS Center. They include but are not limited to 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 cycle. Notifications of requests to use Archived Collaborative Study Datasets for anything other than the originally intended analyses should be submitted through the above 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. Requests to use Ongoing Collaborative Study Datasets for anything other than the originally intended analyses should be submitted through the above procedures. 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 12 months following the end of data collection, whichever comes first.

New collaborative studies can be implemented during a grant cycle. Please see the BMS Standard Operating Procedure regarding peer review of module projects (currently under review) for further detail on the internal module peer review

process. Newly proposed research studies that have not undergone outside peer review as part of the NIDILRR grant proposal review process should follow the Peer Review Policy.

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 PI is encouraged to follow the notification process before submission for such funding. However the detailed hypotheses and methods need not be disclosed.

XI. *Public Use:*

Refer to the BMS Standard Operating Procedure 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.

Training requirements:

None

Compliance:

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:

None

History:

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.

8/19/16—Revised to reflect discussion after year 1 if project has not proceeded and forfeit after year 3.

Review schedule:

Review every year

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

STANDARD OPERATING PROCEDURE (SOP) #602 FORM
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., 1 record for each participant at each time-point) or long (i.e., only 1 record per participant and all data that is collected at more than 1 time-point re-name):

- stacked long

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:

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: