

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

STANDARD OPERATING PROCEDURE (SOP) #604

SOP #604	Title: External Request for BMS National Database and Archived Collaborative Study Datasets SOP and Form	
Approved: BMS Project Directors		Effective Date: 4/24/2012
Attachments: External Request for BMS National Database and Archived Collaborative Study Datasets: Request and Data Use Agreement Form		Revised Date: 3/31/2017
Forms: External Request for BMS National Database and Archived Collaborative Study Datasets: Request and Data Use Agreement Form		Review Date:
Review Committee: BMS Project Directors		

Introduction:

The National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) has supported the collection of data from participants in the Burn Model System (BMS) Centers Program, a collaboration of institutions across the country collecting data for research on outcomes after a burn injury. The result of this collaboration is a unique well-characterized population of subjects with uniformly collected data. The BMS Centers Program has a responsibility to the public in general, and to the scientific community in particular, to encourage scientific use of the BMS National Database and Archived Collaborative Study Datasets as rapidly as possible, subject to appropriate terms and conditions. This document outlines the policies for data access, use and publication for those who desire to use the BMS National Database (and Archived Collaborative Study Datasets) and are not a funded data collection site for the BMS, i.e., the general scientific community.

The BMS Centers have made a substantial long-term contribution in establishing and maintaining the BMS National Database. NIDILRR and the BMS strongly encourage appropriate collaborative relationships between outside investigators and the BMS investigators and they require proper acknowledgement of the contributions of the BMS investigators. It has been the expectation of both NIDILRR and the BMS Centers that the de-identified BMS National Database be made available to the general scientific community. To request data, the requestor [i.e., the principal investigator (PI)] should send an email to the Project Director of the BMS National Data and Statistical Center (NDSC) (see <http://burndata.washington.edu> and click on Contact in the menu) together with a completed request form (*External Request for BMS National Database and Archived Collaborative Study Datasets: Request and Data Use Agreement Form*). This form will contain information on the affiliation of the PI, collaborators, and

research purpose, among other things. After receiving this request, the NDSC will work in partnership with the Project Directors of the BMS centers to review the request and to make a judgement regarding access. The judgement will be based on the information provided and on scientific overlap with existing approved proposals. It is anticipated that most requests will be reasonable and can be approved rapidly, and that only a few will need clarification. In the rare instance that the review process leads to concern regarding the intended purpose or use of the research, the concerns will be forward to the NIDILRR Program Manager of the BMS Centers Program for a decision. Neither the NDSC nor the BMS Centers will monitor IRB compliance by the requestor. However, requestors will be asked to provide IRB numbers and expiration dates on the final version of the request and data use agreement form.

Purpose:

To define the process by which the general scientific community can gain access to the BMS National Database or an Archived Collaborative Study Dataset.

Scope:

All staff, students and other related personnel not involved in the NIDILRR-funded BMS Centers or Follow-up Centers who wish to use data from the BMS National Database or Archived Collaborative Study Datasets. This would include previously funded BMS Centers that are no longer funded and no longer contributing follow-up data to the BMS National Database.

Responsibilities:

All BMS Centers, BMS Follow-up Centers, and the BMS National Data and Statistical Center will abide by this procedure.

Procedure:***Requesting data:***

Requestors will complete a request and data use agreement form after viewing the data dictionary for variables available for analysis (*External Request for BMS National Database and Archived Collaborative Study Datasets: Request and Data Use Agreement Form*). This form is available for download at <http://burndata.washington.edu> and may be emailed or faxed to the Project Director of the BMS NDSC (see <http://burndata.washington.edu/> and go to contacts).

1. The request and data use agreement form will be posted to the BMS listserv by the BMS NDSC. The BMS Project Directors will review the request primarily for PI affiliation, scientific purpose, and scientific overlap with existing approved projects. A deadline date for comments, concerns, and votes of approval from the BMS Project Directors will be provided by the NDSC. Approval of the data request will be by majority vote of the BMS Project Directors.
2. If the request is approved by the BMS Project Directors: The request and the recommendation(s) from the BMS Project Directors will be posted to the BMS Listserv by the NDSC. This is primarily to solicit collaborators if the PI is

interested in having collaborators. Note: Collaboration with BMS investigators is encouraged, but not required.

3. After the proposal has been posted to the BMS Notification Listserv for 10 working days, the NIDILRR BMS Program Manager will make the final decision regarding approval of the proposal with feedback from the NDSC and BMS Project Directors.
4. If the request is approved, the PI will work with the BMS NDSC to detail the proposal so that an appropriate de-identified dataset can be released to the PI. Alternatively, the PI may request that the NDSC run the analyses, in which case the NDSC is eligible for reimbursement from the requestor for the time and resources utilized to conduct such analyses.

During analysis:

The PI should send annual updates to the BMS NDSC, including the name of the PI, title of the project, progress on the project, and an updated anticipated completion date. If the project is not completed or moving forward with significant progress by three years after the approval date, the project will be released to other investigators to take a lead on and complete.

BMS Resources Available:

When sending the approved dataset, the BMS NDSC provides information about that dataset. Additionally, the BMS NDSC is available to provide ongoing information about the dataset, variables, information about coding and how data is collected if external requestors have questions beyond the data dictionary. The BMS NDSC and the BMS do not have the resources to provide free statistical support or analyses for external centers. However, statistical services are available for a fee; if interested in this service, indicate so to the NDSC when requesting data by filling out the separate attachment, External Request for NDSC Analysis Form.

Publication Policy:

The BMS NDSC and the BMS Project Directors will be charged with the administrative review of manuscripts as defined below. Neither of these parties intends to review the manuscripts for scientific quality. As part of the request and data use agreement form, investigators will be asked to agree to a publication policy as follows:

1. All manuscripts will accurately describe the methods of data collection for the BMS National Database or Archived Collaborative Study Datasets.
2. Any dissemination of the study findings should include proper acknowledgement of the BMS and NIDRR support. That is, all manuscripts, posters, and presentations will add the following acknowledgement to the published product:

“The Burn Model System National Database [or the ‘name of the Archived Collaborative Study Dataset’] was supported by the U.S. Department of Health and Human Services, National Institute on Disability, Independent

Living, and Rehabilitation Research (NIDILRR) in collaboration with the NIDILRR- funded Burn Model System (BMS) Centers. However, these contents do not necessarily reflect the opinions or views of the BMS Centers, NIDILRR or the U.S. Department of Health and Human Services.”

3. The PI will submit manuscripts to the BMS National Data and Statistical Center for administrative review at least two weeks to submission for publication. The National Data and Statistical Center will forward the manuscript submission to the BMS Project Directors for their review. This review is not intended to be scientific, but rather administrative to ensure that the terms of this user agreement have been fulfilled and that the data collection methods for the BMS Centers have been accurately described. The National Data and Statistical Center and the BMS Project Directors will maintain confidentiality of all manuscripts, abstracts and presentations.
4. The PI will apprise the BMS National Data and Statistical Center of acceptance or rejection of abstracts, manuscripts, and presentations.
5. The PI will provide the URL and complete citation for any published abstract, manuscript, or presentation using data from the BMS National Database or the Archived Collaborative Study Datasets to the BMS National Data and Statistical Center when available.

Unusual Situations:

It is expected that users of the BMS National Database and Archived Collaborative Study Datasets will follow these guidelines in good faith and that analyses will be of reasonable quality. As earlier stated, the BMS National Data and Statistical Center and the BMS Project Directors do not intend to review abstracts or manuscripts for scientific quality. However, we do anticipate the possibility of some unusual circumstances.

- 1. Failure to Follow the Data Use Agreement.** If users inadvertently violate the User Agreement, corrective action should be taken as soon as infractions are discovered. If users willfully violate the Data Use Agreement, NIDRR and/or the BMS National Data and Statistical Center will revoke current and future access to the BMS National Database and Archived Collaborative Study Datasets.
- 2. Fraudulent Use of the Data.** Should the BMS Project Directors or the BMS National Data and Statistical Center discover an attempt to publish data obtained fraudulently, immediate steps will be taken to secure the breach or end the violation. This may include discontinuing the user’s data access and or reporting the violation, and reporting scientific misconduct to the violator’s institution and/or relevant professional organizations and/or scientific institutions.

Grievances:

Any grievances should be made to the NIDILRR Program Manager of the BMS Centers Program.

Compliance:

All non-BMS Center users of the BMS National Database or Archived Collaborative Study Datasets must comply with this procedure.

References:

None

History:

4/12/12—This SOP replaces Policies 1998-03 and 2009-0001.

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

9/19/2016—Edited to reflect resources available for external requestors and to add a three-year limit on projects.

3/31/2017—Edited to clarify that the NIDILRR Project Manager makes the final decision about an external data request.

Review schedule:

Review at least every 5 years.

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External Request for BMS National Database and Archived Collaborative Study
Datasets: Request and Data Use Agreement Form

Note: This form should be used for requesting use of the BMS National Database or Archived Collaborative Study Datasets by the general scientific community.

Purpose of use (check all that apply): []

Research

[] Other (specify): _____

Dataset to be used (check all that apply): []

BMS National Database

[] Archived Collaborative Study Dataset (specify): _____

Principal investigator's name: _____

Principal investigator's position: _____

Principal investigator's primary institutional affiliation: Type and Name

(check one):

[] Non-profit organization; Name: _____ []

For-profit organization; Name: _____

[] Government agency; Name: _____

[] Other (specify): _____ Name: _____

Principal investigator's address:

Principal investigator's email:

Collaborators' names (after each name, please include the collaborator's primary institutional affiliation in parentheses):

Today's date:

Project start date:

Projected completion date:

Date last updated (if applicable):

Proposed Research:

Provide a brief summary (no more than 4 pages) of the proposed work to be completed with these data. Please follow the format below:

Title of project Key words

Background/Introduction

Study aim(s)

Research hypotheses

Methods

Study sample

Primary outcome measures Secondary outcome

measures Covariates/confounding

measures/variables Data analysis plan

Sample size calculation

IRB approval numbers and expiration dates (not necessary for initial submission, but required prior to release of the data)

Dissemination plan (choose all that apply): []

Publication

[] Presentation

[] Other (specify): _____

Data Use Agreement

I (the PI named above) request access to data from the Burn Model System (BMS) National Database and/or the BMS Archived Collaborative Study Datasets for the purpose specified above and agree to the follow terms:

1. I will receive access to de-identified data and will not attempt to establish the identity of, or attempt to contact, any of the subjects from whom these data were collected.
2. I will not further disclose these data beyond the uses outlined in this Agreement and in my data request described above in this request.
3. I will promptly notify the BMS National Data and Statistical Center of any substantive changes to the proposed research project or of any new projects to be initiated with the requested data. Such notification will consist of a new project description (i.e., the submission of a new *External Request for BMS*

National Database and Archived Collaborative Study Datasets: Request and Data Use Agreement Form).

4. I will require anyone on my research team who utilizes these data to comply with this data use agreement.
5. I will provide annual updates on the progress of this project to the BMS National Data and Statistical Center.
6. I will comply with any rules and regulations imposed by my institution and its Institutional Review Board (IRB) in requesting and using these data.
7. I agree that the use of the data for this request is limited to two years and after such time a new request and data agreement form (*External Request for BMS National Database and Archived Collaborative Study Datasets: Request and Data Use Agreement Form*) should be sent to the BMS National Data and Statistical Center for re-approval.
8. I will report any use or disclosure of the data not provided for by this Agreement of which I become aware within 15 days of becoming aware of such use or disclosure.

If I publish abstracts or manuscripts (papers) using data from the BMS National Database or Archived Collaborative Study Datasets, I agree to the following:

1. I will describe the methods of data gathering used for the BMS data.
2. I will add the following acknowledgement to the published product:

“The Burn Model System National Database [or the ‘name of the Archived Collaborative Study dataset’] is supported by the U.S. Department of Education, National Institute on Disability and Rehabilitation Research (NIDRR) in collaboration with the NIDRR- funded Burn Model System (BMS) Centers. However, these contents do not necessarily reflect the opinions or views of the BMS Centers, NIDRR or the U.S. Department of Education.”

3. I will submit manuscripts to the BMS National Data and Statistical Center for administrative review two weeks prior to submission elsewhere. This review is not intended to be scientific, but rather administrative to ensure that the terms of this User Agreement have been fulfilled and that the data collection methods for the BMS Centers have been accurately described. The BMS National Data and Statistical Center and the BMS Project Directors will maintain confidentiality of abstracts, manuscripts, and presentations.
4. I will apprise the BMS National Data and Statistical Center of acceptance or rejection of abstracts, manuscripts, and presentations.
5. I will provide abstracts, manuscripts, and presentation citations to the BMS National Data and Statistical Center upon acceptance.
6. I will provide the URL and complete citation for any published abstract, manuscript or presentation using BMS data to the BMS National Data and Statistical Center when available.

I understand that failure to abide by these guidelines will result in termination of my current and future privileges to access data from the BMS National Database and Archived Collaborative Study Datasets. Should I try to publish data from the BMS National Database or Collaborative Study Datasets fraudulently or breach this Data Use Agreement, immediate steps will be taken to secure the breach or end the violation. This may include discontinuing the user's data access and/or reporting the violation, and reporting scientific misconduct to the violator's institution and/or relevant professional organizations and/or scientific institutions.

PI Signature

Date