Beneit urn Model Systems National Data and Statistical Center

STANDARD OPERATING PROCEDURE (SOP) #604

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Introduction:
The National Institute on Disability and Rehabilitation Research (NIDRR) 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. NIDRR 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 NIDRR 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
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 NIDRR-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](http://burndata.washington.edu) and may be emailed or faxed to the Project Director of
the BMS NDSC (see [http://burndata.washington.edu/](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 NIDRR BMS Program Manager will make the final decision regarding approval of the proposal with feedback from the NDSC and BMS Project Directors.

4. 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.

5. If the request is not approved by the BMS Project Directors: If the request is not approved by the BMS Project Directors, the request and the concerns of the BMS Project Directors (including those of the Project Director of the NDSC) will be referred to the NIDRR Program Manager for a decision.

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.

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 Education, National Institute on Disability and Rehabilitation Research (NIDRR) in collaboration with the NIDRR-funded Burn Model Systems (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. 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 NIDRR 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

Review schedule:
Review at least every 5 years.
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 Systems (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