

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

**STANDARD OPERATING PROCEDURE (SOP) #604**

<b>SOP #604</b>	<b>Title:</b> External Request for BMS National Database, Public Access Datasets, and Archived Collaborative Study Datasets SOP and Form	
<b>Approved:</b> BMS Project Directors		<b>Effective Date:</b> 4/24/2012
<b>Attachments:</b> <ul style="list-style-type: none"> <li>• External Request for BMS National Database and Archived Collaborative Study Datasets: Request and Data Use Agreement Form</li> <li>• BMS Database Information for Data Request Submissions</li> </ul>		<b>Revised Date:</b> 2/28/2024
<b>Forms:</b> External Request for BMS National Database and Archived Collaborative Study Datasets: Request and Data Use Agreement Form		<b>Review Date:</b>
<b>Review Committee:</b> 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 since 1994. The BMS Centers Program is 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 dataset with comprehensive discharge and outcome data on burn survivors with moderate to severe burn injury. 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 extensively 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 who 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 the use of the BMS data by outside investigators, as well as appropriate collaborative relationships between outside investigators and the BMS investigators. Since its inception, it has been the expectation of both NIDILRR and the BMS that the de-identified data in the BMS National Database be made available to the general scientific community. The data in the BMS National Database are available in two forms: limited data set with a data use agreement and de-identified public dataset. These can be accessed by:

- 1) Submitting a request for limited data set with data use agreement, that outlines

research questions and lists the BMS variables needed to answer the research questions;

- 2) Downloading the de-identified public dataset from the BMS National Data and Statistical Center (NDSC) website (<http://burndata.washington.edu>).
- 3) Contacting the BMS NDSC ([burndata@uw.edu](mailto:burndata@uw.edu)) to request the published dataset. The public dataset contains data collected up to two years prior to the dataset publication date

Access to the BMS data requires users to agree to terms of use prior to accessing the dataset, as well as to comply with BMS branding policies (BMS SOP #608, which can be found here: <http://burndata.washington.edu/standard-operating-procedures>), where applicable.

The data access is further described in the “Methods for Acquiring BMS Data” Section, below.

### **Purpose:**

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

### **Scope:**

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The scope of this SOP applies to 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 includes previously-funded BMS Centers that are not currently funded but are contributing data to the BMS National Database.

### **Responsibilities:**

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All non-BMS researchers interested in accessing the database will abide by these procedures. BMS and BMS NDSC staff will follow the procedures accordingly when an external request is made.

### **Methods for Acquiring BMS Data:**

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- **Request for limited data set with data use agreement.** A Limited Data Set, including data collected up to the date of the request, is available to non-BMS researchers, such as those seeking BMS collaboration. A Limited Data Set is stripped of all HIPAA-defined identifiers except age, dates, city, state or zip code. To acquire the data, the user sends an email to the BMS NDSC ([burndata@uw.edu](mailto:burndata@uw.edu)) with a completed request form; form is available at <http://burndata.washington.edu/about-database> (*External Request for BMS National Database and Archived Collaborative Study Datasets: Request and Data Use Agreement Form*). This form requests information on the affiliation of the PI and collaborators, and the research purpose, among other things. Prior to completing this request, review the information sheet titled “BMS Database Information for Data Request Submissions,” which is attached to this SOP. This

provides important information about the BMS database, including information about the timeline of data collection and about the unique characteristics of the BMS pediatric dataset.

1. After receiving this request, the NDSC will work in partnership with the Project Directors of the BMS to determine whether the research question(s) of the proposed project can be answered by the data requested and to assess potential scientific overlap with existing approved proposals. Further information about the review and approval process can be found in the “Procedure for External Request of Data” Section, below.
2. **De-Identified Public Dataset:** Once a year, the BMS NDSC builds and makes available a public dataset that includes de-identified data collected up to two years prior to the public dataset publication date. The public BMS dataset is freely available by contacting the BMS NDSC ([burndata@uw.edu](mailto:burndata@uw.edu)) or by downloading it from the BMS NDSC website (<http://burndata.washington.edu>). The public dataset is stripped of all HIPAA-defined identifiers, including names, geographic subdivisions smaller than a state, elements of dates (except year) related to an individual, telephone numbers, fax numbers, email addresses, social security numbers, and medical record numbers.

Conditions of use: Requesters must agree to terms of use and to comply with BMS branding policies prior to accessing the dataset. However, no permission from the BMS is required to access/use the publicly available dataset. To minimize duplication of efforts, the BMS maintains a current list of in-progress studies and publications online, which can be accessed here:

<http://burndata.washington.edu/publications-progress>  
<http://burndata.washington.edu/pubs>

Users interested in accessing more current data (less than two years old) can request a dataset via the request for limited dataset procedure, outlined below.

### **Procedure for External Request of Data (as referred to in Section 1, above):**

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#### ***External Request of data:***

External users will complete a request and data use agreement form after reviewing the data dictionary to understand what variables are available for analysis (*External Request for BMS National Database and Archived Collaborative Study Datasets: Request and Data Use Agreement Form*) and after reviewing the “BMS Database Information for Data Request Submissions.” The data use agreement form is available for download at <http://burndata.washington.edu/about-database>. Completed request forms may be emailed to the BMS NDSC ([burndata@uw.edu](mailto:burndata@uw.edu)).

Once the request is received, the following steps will be taken:

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 whether BMS data can address the proposed project, and to check for scientific

overlap with existing approved projects. Also, collaborators within the BMS will be solicited, if the user indicated interest in having collaborators. Note: Collaboration with BMS investigators is encouraged, but not required.

2. If there are no concerns about whether BMS data can be used answer the proposed research questions or about overlap with existing projects are expressed within the 10 day comment period, the NDSC will provide the dataset to the user. No vote is necessary if no concerns are raised during the comment period. If issues are raised, they will be discussed by the BMS Project Directors and a vote will be held to decide whether to provide the data. In case of a tie, the NIDILRR BMS Program Manager will make the final decision. The user will be notified and the final decision will be posted to the BMS listserv.
3. Neither the BMS NDSC nor the BMS Centers will monitor IRB compliance by the user. However, users will be asked to provide IRB numbers and expiration dates on the final version of the request and data use agreement form.
4. The NDSC will provide to the user the de-identified dataset that includes the variables. All relevant information, including metadata, such as data dictionary and codebooks, will also be provided by the NDSC. Alternately, the user may request that the NDSC staff run the analyses. The NDSC staff will consider whether the analyses can be completed in a timely manner considering their existing workload. If the NDSC staff agree to conduct the analyses, it is eligible for reimbursement from the user for the time and resources utilized to conduct such analyses (see BMS Resources Available Section, below, for more information).
5. As a condition of use, the user agrees to send annual updates to the current BMS NDSC, including the name of the lead and collaborating authors, title of the project, progress on the project, and an updated anticipated completion date. If the project has not been completed within 3 years of request approval, the BMS NDSC staff will notify the user that the project has exceeded the time limit specified in the data use agreement for significant progress and that the research hypotheses they were investigating are now released to the general public as well as the BMS investigators. If others within the BMS or the broader research community are interested in exploring similar research hypotheses the dataset and the project/topic will be made available to other interested parties.

### **BMS Resources Available:**

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When sending the approved dataset, the BMS NDSC provides information about that dataset. Additionally, the BMS NDSC staff are available to provide ongoing support related to the dataset, variables, information about coding and how data is collected if external users 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, the user can request the services by filling out the External Request for NDSC Analysis Form.

### **Publication Policy:**

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If the use of BMS data results in a manuscript/poster/abstract/dissertation or other form of publication, a draft of the manuscript/abstract/dissertation or other output

must be provided to the BMS-NDSC prior to submission for publication. The BMS NDSC and the BMS Project Directors will review the manuscript to ensure that:

1. All manuscripts accurately describe the methods of data collection for the BMS National Database or Archived Collaborative Study Datasets.
2. The manuscript or any other form of dissemination includes proper acknowledgement of the BMS and NIDILRR 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 user will submit manuscripts to the BMS NDSC for administrative review at least two weeks to submission for publication. The BMS NDSC 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.
4. The BMS NDSC and the BMS Project Directors will maintain confidentiality for all manuscripts, abstracts, and presentations. The research findings of the external manuscripts will not be released to the public or presented to any BMS stakeholders until the manuscript has been published.
5. The user will apprise the BMS NDSC of acceptance or rejection of abstracts, manuscripts, and presentations.
6. The user 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 NDSC within 90 days of when it becomes available. Once the manuscript has been published, the citation will be shared on the BMS NDSC website.

### **Redistribution of Data:**

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BMS NDB should only be shared with other AUTHORIZED USERS.

1. For each approved data request, each and every person who will use the BMS NDB for the purposes of the approved data request must complete, sign and submit to the NDSC a duplicate version of this form, and agree to these Terms of Use to become an AUTHORIZED USER.
2. Do not share the BMS NDB data unless the recipient submits a duplicate request and agrees to these Terms of Use Sharing the BMS NDB with a person who is not an AUTHORIZED USER is a violation of this standard operating procedure.

3. In the event that a person who is not an AUTHORIZED USER obtains the BMS NDB dataset, promptly notify the NDSC of the data accessed and the person/entity who received it.

There is no redistribution or sharing of the BMS NDB with unauthorized person or entity for any reason, except when required or encouraged for journal publication or by research funding agencies. Journal editors or grant makers may, in certain circumstances, request a copy of the data on which a paper or report is based; in which case, the AUTHORIZED USER must notify the NDSC in writing prior to redistribution/sharing for this purpose

### **Unusual Situations:**

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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 scientifically rigorous quality. As earlier stated, the BMS NDSC and the BMS Project Directors do not intend to review abstracts or manuscripts for scientific quality. However, the BMS anticipates the possibility of some unusual circumstances, including:

1. **Failure to Follow the Data Use Agreement.** If users inadvertently violate the Data Use Agreement, corrective action should be taken as soon as infractions are discovered. If users willfully violate the Data Use Agreement, NIDILRR and/or the BMS NDSC 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 NDSC staff discover an attempt to publish data obtained or used 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 scientific misconduct to the violator's institution and/or relevant professional organizations and/or scientific institutions.

### **Grievances:**

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

### **Compliance:**

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

### **References:**

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None

### **History:**

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4/12/2012—This SOP replaces Policies 1998-03 and 2009-0001

9/30/2015—Updated to replace all references to NIDRR with NIDILRR.

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

5/20/2019—Edited to include information about public access to data.

6/22/2022—Revised to include redistribution of data section and GeoCode/linking dataset information.

2/28/2024—Added information sheet titled “BMS Database Information for Data Request Submissions”.

**Review schedule:**

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Review at least every 5 years.

## **BMS Database Information for Data Request Submissions**

This document is for people who have read the factsheet about the BMS Database and are ready to apply for a data request. Before you complete the data request form please read the following information and examine the available resources listed here. This will ensure that there are no delays in receiving your dataset due to data requests that overlap with existing studies or research questions that cannot be answered using available Burn Model System (BMS) data.

### Important Information About the Database:

- An overview of the BMS, including its purpose and data collection procedures (e.g. inclusion and exclusion criteria), can be found in this publication: Amtmann, D., McMullen, K., Bamer, A., Fauerbach, J. A., Gibran, N. S., Herndon, D., ... & Miller, A. C. (2020). National institute on disability, independent living, and rehabilitation research burn model system: review of program and database. Archives of physical medicine and rehabilitation, 101(1), S5-S15. <https://pubmed.ncbi.nlm.nih.gov/28989076/>
- **Major changes were made to the data collection forms in 2015.** Many variables were added and removed from the BMS database at this time. Please refer to the BMS timeline (see below) to see what changes were made. Other changes were made at other timepoints (e.g. 2006, 2022), but 2015 saw the most changes.
- The **pediatric dataset** has a number of unique characteristics. If you are planning to request pediatric data please be aware of the following:
  - The majority of pediatric participants (55%) were enrolled at Shriners Hospital at the University of Texas Medical Branch (UTMB) in Galveston, Texas. The majority of these participants do not reside in the United States and traveled from Mexico to receive treatment at Shriners. These participants tended to have more severe burns than the pediatric participants enrolled at other treatment sites. Shriners also paid for the care received for most of these participants rather than traditional insurance. Important societal characteristics also differ between the US and Mexico (e.g. educational and health systems).
  - A significant percentage (20%) of pediatric participants speak Spanish as their primary language. This percentage is significantly higher (41%) for those participants enrolled after 2015. Because follow-up was better for Shriners' participants from Mexico who received free care from Shriners, the majority (73%) of responses to patient reported outcome measures at follow-up, including PROMIS measures, were in Spanish speaking participants.

### To Do Before Requesting Data:

- Several webinars are available to help you better understand what kinds of data are collected by the BMS, how to go about formulating a research question, and requesting a dataset. **If your familiarity with BMS data is limited, please watch the two brief webinars on "Accessing and using the BMS Database" (Part 1 and Part 2) prior to requesting a dataset:** [BMS Webinars](#).
- Prior to requesting a dataset you must ensure that your research question/hypothesis does not **overlap with ongoing research studies** (if it does overlap your data request may be



denied). You can find a complete list of manuscripts in process utilizing the BMS database here: [Ongoing studies](https://burndata.washington.edu/publications-progress). <https://burndata.washington.edu/publications-progress>

Resources for Formulating Your Data Request:

- **The BMS Timeline** is an ‘at a glance’ big picture summary of what scales and measures are available in the BMS and at what timepoints. This is the easiest way to determine if the variables you are interested in were collected at the same time and for a long enough period to have adequate data (i.e. sample size) to answer your research question. If the timeline shows measures you are interested in were only collected for a few years you may want to ask the data center about the available sample size prior to submission of a data request (by emailing [burndata@uw.edu](mailto:burndata@uw.edu)). [Access the timeline by navigating](https://burndata.washington.edu/about-database) to this webpage <https://burndata.washington.edu/about-database> and scrolling down to the “What is in the database” heading.
- The **data dictionary** contains very specific information about the exact variables collected by the BMS including their specific wording, response choice and coding, timepoints collected, and method of data collection. If you require this level of information about the exact versions of items or scales used by the BMS please reference the data dictionary. [Access the data dictionary by navigating](https://burndata.washington.edu/about-database) to this webpage <https://burndata.washington.edu/about-database> and scrolling down to the “How to Request BMS Datasets” heading.

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

**STANDARD OPERATING PROCEDURE (SOP) #604**

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.*

**To submit this request, email this completed form to [burndata@uw.edu](mailto:burndata@uw.edu).**

**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 (not required but suggested)

**Do you intend to link the BMS NDB with any other datasets?**

Yes

No

If so, please describe the data to be linked to the BMS National Database or Archived or Ongoing Collaborative Database data, 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

**Do you need support from the BMS? If so, what kind of support?**

Statistical support (this may involve expenses to be paid to the BMS NDSC. If you check this box, the BMS NDSC will work with you on the scope of work and any payment required).

Mentorship from BMS researchers (this will not involve any expense to you)

**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*). This notification will be sent via email to burndata@uw.edu.
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 by emailing the update to burndata@uw.edu
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 by emailing burndata@uw.edu.
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 by emailing burndata@uw.edu.

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 National Institute on Disability, Independent Living, and Rehabilitation Research NIDILRR is a Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of this (insert type of publication; e.g., book, report, film) do not necessarily represent the policy of NIDILRR, ACL, HHS, and you should not assume endorsement by the Federal Government..”

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. Manuscripts will be emailed for review to [burndata@uw.edu](mailto:burndata@uw.edu).
4. I will apprise the BMS National Data and Statistical Center of acceptance or rejection of abstracts, manuscripts, and presentations by emailing [burndata@uw.edu](mailto:burndata@uw.edu).
5. I will provide abstracts, manuscripts, and presentation citations to the BMS
6. National Data and Statistical Center upon acceptance by emailing [burndata@uw.edu](mailto:burndata@uw.edu). 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 by emailing [burndata@uw.edu](mailto:burndata@uw.edu)

If I share the BMS NDB, I agree to the following:

1. BMS NDB should only be shared with other AUTHORIZED USERS.
2. Each and every person who will use the BMS NDB for the purposes of the study pertaining to this data use agreement will complete, sign and submit to the NDSC a duplicate version of this form, and agree to these Terms of Use to become an AUTHORIZED USER.
3. If the intended recipient of the BMS NDB data does not submit a duplicate request and agree to these Terms of Use, I will not give them access to the BMS NDB.
4. I will not share the BMS NDB with a person who is not an AUTHORIZED USER.
5. In the event that a person who is not an AUTHORIZED USER obtains the BMS NDB, I will promptly notify the NDSC of the data accessed and the person who received it.
6. There is no redistribution or sharing of the BMS NDB with anyone or any entity for any reason, except that required for journal publication or by research funding agencies. Journal editors or grant makers may, in certain circumstances, request a copy of the data on which a paper or report is based; in which case, I will notify the NDSC in writing prior to redistribution/sharing for this purpose

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.

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PI Signature

Date