Burn Model System
National Data and Statistical Center

STANDARD OPERATING PROCEDURE (SOP) #607

SOP #607	Title: Procedure for Implementing Changes to the Database	
Approved: BMS Project Directors		**Effective Date**:9/20/2012
Attachments: SOP Database Changes Form		**Revised Date:**
Forms: SOP Database Changes Form		**Review Date:** 8/31/2021
Review Committee: BMS Project Directors		

Introduction:

The BMS National Data and Statistical Center (NDSC) will implement significant modifications to the data dictionary and/or the electronic database according to the procedures outlined below. Non-structural changes, such as clarifications of operational definitions and clarifications of data choices, will be made in a timely manner following notification of and approval by the data committee. Structural modifications and/or database or variable changes may be initiated by any of the BMS Centers or by the NDSC. Proposed changes to the database are categorized as Level 1, Level 2 or Level 3, depending on the scope of the proposed change. The allowed frequency and timing of changes to the database vary, depending on the scope of the change.

Purpose:

To institute a standardized policy for implementing changes to the BMS Database ("database").

Scope:

All current BMS centers and the NDSC.

Responsibilities:

All current BMS and NDSC staff who propose to implement changes to the database.

Procedural steps:

The NDSC must obtain approval, as described below, before implementing any changes to the BMS Database. The following describes the levels of revisions and the corresponding procedure.

1. **Level I revisions to the database** are changes that require (a) clarifying of one or more points in an existing data form and/or (b) adding one or more new or improved examples.

a. If a Level I revision is requested, then within 10 business days of the request, the NDSC will prepare a draft revision of the data form(s) and/or data dictionary that will change and send the revised document(s) to the Project Directors for comment and approval. Approval requires majority vote by the BMS Project Directors. In the event of a tie, discussions will be continued until a majority vote can be reached.

b. Within 10 business days of the posting of the revised document(s), each Project Director will respond with his/her vote of approval or with further revision/clarification as appropriate in order to arrive at a final version of the revision.

c. The NDSC will implement the updated syllabus page on the first day of the next data collection quarter. Within 30 days of the beginning of that quarter, the NDSC will post an updated data form on the NDSC website.

2. **Level II revisions of the database** are changes that require adding or deleting codes from an existing variable.

   a. If a Level II revision is requested, then within 10 business days of the request, the NDSC will prepare a draft revision of the affected form(s) and send it to the BMS listserv for comment and approval. Approval requires majority vote by the BMS Project Directors. In the event of a tie, discussions will be continued until a majority vote can be reached.

   b. If the addition or deletion of variable codes will cause data collected in the future to be incompatible with data already in the database (e.g., two codes are collapsed into the same code or a new code is added; both changes would require recoding), the NDSC will also prepare a recommendation regarding how the incompatibility between old data and new data will be handled.

   c. When BMS Project Directors (and additional BMS staff if desired) have had an opportunity to comment on the proposed revisions, the NDSC will prepare a final version for vote by the Project Directors. Approval requires majority vote by the BMS Project Directors. In the event of a tie, discussions will be continued until a majority vote can be reached.

   d. Once the revisions have been approved by the Project Directors, the NDSC will implement the updated data collection on the first day of the next quarter. Within 30 days of the beginning of that quarter, the NDSC will post an updated data form on the website.

3. **Level III revisions of the database** are changes that require adding or deleting variables or changing variable definitions such that substantial changes to the variable's coding scheme is required. The latter is effectively equivalent to adding a new variable and deleting and archiving previously entered data.

a. Requests for Level III revisions may originate from a group or individual. The group or individual must complete the Adding and Deleting Variables Form and submit to the NDSC.

b. Level III revisions will occur a maximum of twice in a five year grant cycle, at the beginning of a new grant cycle and mid-way through a grant cycle.

c. The approval process includes two phases, each of which involves a voting process by the Project Directors: i) initial consideration of variable(s) followed by a vote re: whether to move the variable(s) forward for pilot testing; and ii) final consideration of variable(s) followed by a vote re: whether to include/delete the variable(s) in the database.

    i. The NDSC will collate a list of candidate variables for addition and deletion, and distribute the list to the Project Directors.

    ii. Project Directors will discuss each proposal and cast one vote per variable to determine whether a variable(s) will move forward for pilot testing. In this vote, approval requires majority vote by the BMS Project Directors. In the event of a tie, discussions will be continued until a majority vote can be reached.

    iii. For variables that are approved for pilot testing, data will be collected on a minimum of 20 participants per variable.

    iv. Interested parties will discuss issues discovered while implementing the new data collection tools. This activity will be coordinated by the NDSC. A report will be generated that includes cost estimates for collection along with any concerns or need for clarification. The information included in the report will be made available to and discussed by the Project Directors. A final vote will follow to determine whether the proposed change will be implemented. In this vote, approval requires majority vote by the BMS Project Directors. In the event of a tie, discussions will be continued until a majority vote can be reached.

    v. The first vote (see ii above) typically occurs at a Project Directors' meeting approximately one year before the changes are expected to be implemented, i.e., one year before the start of a new grant cycle and one year before the mid-point in a grant cycle. The second vote (see iv above) occurs following pilot testing, during the Project Directors' meeting approximately 6 months before the changes are expected to be implemented. For example, in April, 2014, Project Directors may vote on whether to pilot test a variable that has been proposed for addition to the database. Pilot testing follows for all variables that receive a majority vote. In November, 2014, Project Directors review and discuss data from pilot testing and vote whether

to include the variable in the database. Implementation of approved changes will begin April, 2015. Variables being considered for addition/deletion for the beginning of a new grant cycle will be posted on the public website with the data dictionary.

d. At least 30 days prior to the changes going into effect, the data center will post a revised data dictionary, data collection forms, etc. to the website.

e. Following the end of the final quarter prior to implementing changes and once all centers have submitted their final pre-change data, the NDSC will make appropriate revisions to the database software and notify centers when their database has been updated and can be used.

f. BMS centers will begin using the revised forms, etc., as of the effective date.

4. **Special Case: Deletion of variables being used in a current project.** There may be a case where a variable(s) is/are suggested to be removed that is/are being used in a specific research project by a group or individual.

a. If this is the case the group/individual must make this known to the NDSC prior to the initial vote by the project directors.

b. When these variables are identified, the NDSC will consolidate the information regarding who is using the variable(s), for which project and at what time they anticipate no longer needing the variable(s). This information will be distributed along with other meeting materials.

c. If the Project Directors approve deletion of these data, the deletion will not occur until after the date specified by the group or individual using the data. All data previously collected for the variables(s) to be deleted will be archived and a new version of the database will be released.

Training requirements:

If new variables are being implemented, the group or person recommending the new variables will be responsible for training data collectors on the collection of new variables. The NDSC will coordinate trainings.

Compliance:

All BMS centers and the NDSC are responsible for adhering to this policy and its procedures.

References:

None

History:

9/20/2012 - This version replaces policy # 1998_01(modifying the BMS database)

Review schedule:

At least every 5 years

Burn Model System
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STANDARD OPERATING PROCEDURE (SOP) #607 FORM

Note: This form is for use by BMS Model System Centers and BMS Longitudinal Follow-Up Centers only.

Recommendation for Adding/Deleting Variables from the National Database:

Person/Group making this request: Contact Person:

Brief Description of the Variable:

1. What is the intent behind the addition or deletion of the variable?

2. Does the variable to be added (or deleted) make a unique contribution as a covariate (i.e. predictor, modifier, mediator) across many important outcome variables?

3. Do the psychometric properties of this variable make it a "good" (or bad, for deletions) variable for measuring the construct of interest?

4. Is this variable of intrinsic importance as a long-term outcome?

5. The core national database was designed for critical long-term data collection where modules were designed to be time-limited data collection with specific research questions; does this variable support a research goal that cannot be met through a modular approach?

6. How "costly" (in terms of length of time and collection approach) is it to collect the proposed variable?