603b Implementing Changes to the National Database

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<tr>
<td>Review Committee: Planning</td>
<td>Start Date: 9/8/1999</td>
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<tr>
<td>Attachments: Timeline for Implementing Changes to the National Database (addendum)</td>
<td>Last Revised Date: 10/29/2018</td>
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<tr>
<td>Forms: 603bf Implementing Changes to the Database Form</td>
<td>Last Reviewed Date: 3/21/18</td>
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Introduction:
The TBIMS has established criteria for implementing changes to the TBIMS National Database (NDB).

Purpose:
To institute a standardized policy for implementing changes to the NDB.

Scope:
All current TBIMS centers and the NDSC.

Responsibilities:
All current TBIMS and NDSC staff who wish to implement changes to the NDB.

Definitions:
Variable – a single coded variable (e.g., for example, EduYears – Years of Education).
Variable groups – a group of variables on a common topic, or an instrument with multiple items, with all variables within the group coded individually with similar or different coding schemes (e.g., Employment Status is a variable group containing 2 variables, Emp1 – Employment Status: Primary and Emp2 – Employment Status: Secondary. GOSE – Glasgow Outcome Scale – Extended is a variable group containing 21 variables, GOSCommands – Obey Simple Commands/Say Words, GOSAssistAll – Assistance is Essential at Home, etc.). Codes – each variable has a number of codes with corresponding definitions (e.g., the variable DrugsF – Drug Use has 5 codes 1 = No, 2 = Yes, 6 = Variable DNE, 7 = Refused, 9 = Unknown).

Procedural steps:
The NDSC must obtain TBIMS approval, as described below, before implementing any changes to the TBIMS National Database. The following describes the levels of syllabus revisions and the corresponding procedure.

1. **Level I syllabus revisions** are changes that require (a) clarifying of one or more points in an existing syllabus page and/or (b) adding one or more new or improved examples. These types of revisions do not involve adding or deleting any variable groups, variables or codes, regardless if they involve additional data collection from
a participant (e.g., method of interview data collection). They can involve clarifying definitions, adding or deleting items included in a code (e.g., adding or deleting items included in code 4 correctional institution, such as a half-way house, for the variable residence at injury).

a. If a Level I syllabus revision is required, within 10 business days of learning that a Level I revision is required, the NDSC will prepare a draft revision of the syllabus page(s) that have changes and send it to the Data Committee for comment and approval.

b. Within 10 business days, the Data Committee will respond with approval or further revision/clarification as appropriate in order to arrive at a final version of the revision.

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

2. **Level II syllabus revisions** are changes that require adding or deleting codes from an existing variable, or require deleting variables or variable groups. It does not include adding variable groups or single variables, regardless if they involve additional data collection from a participant.

a. If a Level II syllabus revision is required, within 10 business days of learning that a Level II revision is required, the NDSC will prepare a draft revision of the syllabus page(s) that have changes and send it to the Data Committee for comment and approval.

b. If the addition or deletion of variable codes or deletion of variables/variable groups 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. Once the Data Committee has had an opportunity to comment on the proposed revisions, the NDSC will prepare a final version for Data Committee majority vote.

d. Once approved by the Data Committee, the Data Committee chair will recommend approval by the Project Directors by majority vote (1 vote per center) via email or in-person at the Project Directors meeting.

e. Once approved by the Project Directors, the NDSC will prepare and distribute updated syllabus pages and data collection forms for Centers to obtain IRB approval. The approved changes will go into effect the quarter following the next data submission (e.g., changes approved June 15; next data submission June 30; NDSC sends forms to centers July 15 for IRB submission; data submission September 30; changes go into effect October 1).
3. **Level III syllabus revisions** are changes require adding variable groups, variables or changes in the variable’s coding scheme beyond adding codes. Variable/variable group deletions that are not performed at Level II may also be performed at this level. Level III syllabus revisions will only occur twice in a five year grant cycle to go into effect at the beginning of a new grant cycle and mid-way through a grant cycle. Before the addition or deletion of variables, a Project Director must listen in on a Form II interview to gauge current burden of data collection.

   a. Discussion of variable additions/deletions will begin 1 year prior to the final vote, variable piloting will start six months before the final vote, and the approved addition/deletion of variables will go into effect the quarter following the next data submission.

   b. Requests for Level III revisions can originate in a SIG, Module or Committee. A SIG, Module, or Committee may propose a slate of variables or individual variables and must complete the Adding and Deleting Variables Form and submit to the Planning Committee 1 month after the Project Directors meeting where initial discussions took place.

   c. The Planning Committee will summarize all proposed variable changes, email those to the TBIMS, and conduct a survey to determine any early questions/concerns with proposed changes 1 month after the Forms are due. Responses to that survey are due to the Planning Committee 2 weeks after receipt.

   d. The Planning Committee will disseminate the survey results to the TBIMS 1 month after survey due date. The proposing SIG, Module or Committee will have to respond to any questions/concerns in writing to the Planning Committee 1 month later. The Planning Committee will disseminate any SIG, Module, Committee responses to the TBIMS 1 month after that.

   e. The Project Directors will vote on which newly proposed variables should be piloted, and discuss any questions/concerns about variables proposed for deletion. Approval of new variables to be piloted must pass with a simple majority vote (9/16).

   f. All approved variable groups and variables will be pilot tested by a sufficient number of centers (at least 3) with a sufficient number of cases to determine feasibility. The piloting will occur within the context of the currently approved variables in order to evaluate impact on length of interviews, burden to participants and data collectors, and redundancy perceived by participants. Adjustments to reduce or minimize burden should also be piloted. This activity will be coordinated by the NDSC and the proposing group, and will be completed 4 months after the proposed variable additions/deletions vote at the PD Meeting. Two weeks after variable data is submitted to the NDSC, a report will be made to the Planning Committee that will include a summary of
data collected, cost estimates for collection along with any concerns or need for clarification. If an approved variable group or variable has already been pilot tested (meeting the definition above) in its proposed form (for example within a module), no further pilot testing is necessary.

g. The Planning Committee will immediately disseminate the report to the TBIMS, and conduct a survey to determine any final questions/concerns with proposed variable additions. Responses to the survey are due to the Planning Committee 2 weeks after receipt.

h. The Planning Committee will disseminate the survey results to the TBIMS 1 week after the survey due date. The proposing SIG, Module or Committee will have 2 weeks to respond to any final questions/concerns in writing to the Planning Committee. The Planning Committee will then disseminate any questions/concerns to the TBIMS 1 week after.

i. The Planning Committee will consolidate a list of candidate variables for addition and deletion and present this to the Project Directors for a super majority vote (11/16) on each variable change to be conducted at the Project Directors Meeting.

j. Variables being considered for addition/deletion for the beginning of a new grant cycle will be posted on the public website with the database syllabus.

k. The NDSC will send a summary of variable changes and revised data collection forms to TBIMS centers within 1 month so they can submit these revisions for IRB approval.

l. At least 30 days prior to the changes going into effect, the NDSC will coordinate any necessary training for data collectors.

m. The approved changes will go into effect the quarter following the next data submission.

n. TBIMS centers and follow-up centers will begin using the revised forms, data entry, etc., as of the effective date.

4. **Off Cycle Changes to the National Database** are any proposed Level III changes to the National Database that deviate from the procedure described above.

   a. Off cycle changes should only be considered in the case of emerging scientific issues that arise, and must be acted upon outside of the regular Level III change cycle.

   b. Must be initiated through an existing committee, module or SIG.
c. Provide a brief written proposal to the Planning Committee including a variable description, rationale, estimated burden on participants and data collectors. Also include the names of the sites willing to pilot the variables (at least 3 sites) with a prespecified number of participants that has been determined to be sufficient to assess feasibility.

d. Planning committee votes on whether to proceed with piloting

e. Piloting is conducted. The piloting should occur within the context of the currently approved variables in order to evaluate impact on length of interviews, burden to participants and data collectors, and redundancy perceived by participants. Adjustments to reduce or minimize burden should also be piloted.

f. Summary of pilot results are sent to the Data Committee, who reviews and comments on any concerns raised by the pilot. The pilot results and Data Committee review are sent to the Planning Committee.

g. Planning committee votes.

h. If there is an affirmative vote from Planning Committee, the variable is added to the database.

i. At which time, the data collected in the pilot can be considered to be added to the National Database retrospectively.

j. The resources needed by all collaborating centers and the NDSC, and timeline for the proposed project should be clearly delineated.

Training requirements:
If new variables are being implemented, the SIG, Module or Committee recommending the new variables will be responsible for training data collectors on the collection of new variables. The NDSC will coordinate trainings.

Compliance:
All TBIMS centers, longitudinal follow-up centers and the NDSC are responsible for adhering to this policy and its procedures

References:
None

History:

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<th>Action</th>
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<tr>
<td>9/8/1999</td>
<td>Version used to create this SOP</td>
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<tr>
<td>9/16/2008</td>
<td>Transferred to SOP template</td>
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<tr>
<td>9/16/2008</td>
<td>SOP Review Committee Recommended moving sections related to changes to the national database syllabus from SOP 603a – Resolving Data Collection and Coding Questions SOP and sent to Planning Committee for review</td>
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<tr>
<td>12/4/2008</td>
<td>Approved by SOP Review Committee</td>
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<tr>
<td>12/12/2008</td>
<td>Approved by Planning Committee and Project Directors</td>
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6/17/2011  Added text to allow module groups to propose new variables and that approval of data additions/deletions to the database need a super majority vote (11/16).

1/29/2014  Revised level II and III procedure and added addendum/timeline for adding/deleting variables

3/21/18  Revised Level II and III procedures, added definitions, and added a provision for off-cycle changes

10/29/2018  Added requirement of PD listening in on Form II interview to item #3.

10/29/2018  Added items b. through h. to item #4.

Review schedule: At least every 5 years.