



603b	Procedure for Implementing Changes to the TBIMS National Database	
Approved: TBIMS Project Directors	Effective Date:	4/1/2009
Attachments: None	Revised Date:	Transferred to SOP template 9/16/08.
Forms: Adding and Deleting Variables Form	Reviewed Date:	12/12/2008
Review Committee	SOP Committee	

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.

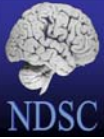
Responsibilities:

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

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.
 - 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.



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- 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.
 - 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 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, within 30 days of the beginning of the second 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 the next second quarter.
 3. **Level III syllabus revisions** are changes that require adding/deleting variables or changes in the variable's coding scheme beyond adding or deleting codes.
 - a. 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 at grant cycle.
 - b. Requests for Level III revisions can originate in a SIG or committee. The SIG or committee must complete the Adding and Deleting Variables Form and submit to the Planning Committee.
 - c. The Planning Committee will consolidate a list of candidate variables for addition and deletion and present this to the Project Directors for majority vote on each variable change to be conducted at the Project Directors meeting (for example, the December, 2009 meeting for changes going into effect mid-cycle 4/1/2010 and at the December 2011 meeting for changes going into effect at the beginning of the new grant cycle October 2012). Variables being



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- considered for addition/deletion for the beginning of a new grant cycle will be posted on the public website with the database syllabus.
- d. All approved variables will be pilot tested by a minimum of two centers with a minimum of 20 participants prior to final vote for approval. This activity will be coordinated by the Data Committee. Upon completion, a report will be made to the Planning Committee that will include cost estimates for collection along with any concerns or need for clarification.
 - e. At least 30 days prior to the changes going into effect, the NDSC will post to the website, revised syllabus pages, data collection forms, etc.
 - f. Following the end of the final quarter prior to implementing changes and once all centers have submitted their final pre-change database, the NDSC will make appropriate revisions to the database software and notify centers when their database has been updated and can be used.
 - g. TBIMS centers will begin using the revised forms, etc., as of the effective date.

Training requirements:

If new variables are being implemented, the SIG 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:

- 1) Version used to create this SOP = 09/08/99
- 2) Transferred to SOP template = 9/16/08
- 3) SOP Review Committee Recommended moving sections related to changes to the national database syllabus from SOP 603a – Resolving Data Collection and Coding Questions SOP = 09/16/08 and sending to Planning Committee for review.
- 4) Approved by SOP Review Committee = 12/04/2008
- 5) Approved by Planning Committee and Project Directors 12/12/2008

Review schedule: At least every 5 years.