Burn Model Systems National Data and Statistical Center

STANDARD OPERATING PROCEDURE (SOP) #609

SOP #609	BMS Module Project Procedures	
Approved: 2/1/2016		Effective Date: 2/1/2016
Attachments: BMS Module Proposal Instructions		Revised Date: 10/1/2017
Forms: BMS Peer Review Form		Review Date:
Review Committee: BMS Project Directors		

Introduction:
Modules are defined as time limited peer reviewed studies involving more than one BMS CENTER.

Purpose:
To define the purpose, formation, and function of the BMS modules. To describe the process for peer review of new module research projects that were not included in original BMS grant applications and therefore, did not undergo peer review. .

Objective:
  I.   To establish procedures for forming new BMS modules.
  II.   To establish procedures for peer review of new BMS modules.

Scope:
  I.   All BMS CENTERS and the BMS NDSC.

Responsibilities:
All CENTERS and the BMS NDSC will abide by this policy and procedure.

Policy and Procedure:

Module Description:
Modules are time limited studies involving more than one BMS CENTER. They are generally observational in nature and focused on a specific aspect of burn injury. The priority for the 2012-2017 grant cycle did not include module research, therefore no modules were proposed in applications for the BMS 2012-2017 grant cycle. (The omission of a module requirement was intended to allow sufficient funds for a new long term data collection requirement for the BMS Database (ie, the addition of data collection at five and ten years post injury, and every five years thereafter). Thus, no CENTERS were required to participate in modules for the 2012-

2017 grant cycle. The 2017-2022 grant cycle did include requirements for module projects. Module forms and data collection are supported by the NDSC.

Ad-hoc Module Development:
Module projects developed post-award have not undergone external peer review since they are not a part of the original grant applications, and therefore the proposers do not have the benefit of a critique by an expert who is free of conflicts of interest. The following procedures establish a process for peer review among the BMS centers to fill that gap, supplemented as needed by outside experts.

Procedure:

1. A proposal for a multi-center collaborative module project emerges from collaborators in at least 2 centers.

2. The idea for the project is sent in draft form via email to the BMS listserv, with the expectation that every effort will be made to incorporate the input and ideas of all centers expressing an interest in collaboration. The NIDRR Project Officer for each of the participating sites must approve the site's participation in the module.

3. The proposal is written using the BMS Module Proposal Instructions (attached) and submitted to the NDSC and the BMS Project Officer.

4. NDSC and NIDRR collaborate to form a Peer Review Panel for each proposed module. Each panel consists of three reviewers with expertise in the proposal's topic areas and/or research methodology/statistics. These reviewers should not have contributed to the proposal. If insufficient expertise is available within the BMS, outside experts may be obtained.

5. Coordinated by the NDSC, panel members independently review the proposal and complete the Review Form (attached). As per the Review Form, they rate each section on a 4-point scale, and give the overall proposal a global rating of 1 to 4, weighing the components as they see fit.

6. Panel Reviews must be returned to the NDSC and the BMS Project Officer within 15 business days (3 weeks) of receipt. A 30 minute teleconference is pre-scheduled for the Review Panel for the week following this deadline.

7. The NDSC distributes the reviews to all panel members prior to the teleconference. The teleconference is used to (a) resolve any major discrepancies between reviewers, (b) highlight the most important needs for revisions, if any, ~~and~~ (c) assign a final global score representing the consensus of the panel, and (d) elect the Review Panel member who will meet with the PIs of the module project to discuss the review.~~.~~

8. And elected member of the Review Panel meets by telephone with the PIs of all participating centers of the module to answer questions on the review, and supply additional detail. Other members of the review panel may join the teleconference if they choose.

9. The entire process from submission of a proposal to the NDSC to receipt of a written review by proposer(s) should take no longer than 2 months.

10. An average of all scores from all raters of 3 or greater indicates that the project may move forward. The proposal, the reviews with any recommendations for change, and the scores will be forwarded by the NDSC to the members who collaborated on the proposal and to the NIDRR BMS Project Officers of all participating centers, with an indication that the project may proceed. A notification of the approved project will also be sent to the BMS listserv, so that all centers may be informed of the new module projects. Anonymity of reviewers will be maintained.

11. An average of all scores from all raters of 2.9 or lower reflects a judgment by the panel that the project as proposed should not go forward. The originators of the proposal may revise and resubmit the proposal to the review panel once. If the score does not exceed 2.9 on the second try, the review process ends for that project. However, an appeal may be made to the NDSC by the Lead Center, if the decision is perceived as inaccurate or unfair. The NDSC will convene the review panel via teleconference call as needed and consider appeals on a case by case basis.

12. Once a project has been recommended and officially approved by NIDRR, the Project Officer of the Lead Center will be the Project Officer for the module.

Training requirements:
None

Compliance:
All BMS centers and the NDSC will comply with this procedure.

References:
None

History:
This SOP was developed to provide a procedure for the development and approval of module projects that were not proposed in the original grant applications, and therefore, did not undergo peer review.

10/1/2017: edited to update the current funding cycle information.

Review schedule: At least every 5 years and at the beginning of each funding cycle.

BMS Module Proposal Instructions

Instructions: *Module leaders fill out this form or create a document for the proposed module project with each of the categories below. The length of the completed form should be up to 5 pages (single spaced). It is not necessary to include formatted references. If you have a longer proposal written for another purpose, e.g. IRB submission, information from it may be included without editing. Submit this to the NDSC.*

Title of project:

PI and lead center:

Collaborators and their centers:

Period during which proposed project will collect data:

Start date:

End date:
Note: Generally this date is the end of the funding cycle, but modules can be renewed by resubmitting this application and following the same process after the start of a new funding cycle if all the PIs involved wish to continue research.

Date this form is submitted to NDSC:

Significance & Anticipated Outcome(s): (knowledge gaps the research is intended to fill; innovative aspects of the research plan):

Research Plan (overview of research design, independent and dependent variables, specific aims, hypotheses, research questions, etc):

Methods (participants: inclusion/ exclusion and anticipated number [power calculations]; procedure and instruments to be used in data collection [attach data collection forms if available]):

Data Analysis Plan (statistical or other analytical methods to be used):
Note: The data analysis plan can be developed with the support and guidance of the NDSC. This section is not voted on by the peer review panel.

BMS Peer Review Form

Instructions: Please use this form to rate the proposal on a scale from 1(poor) - 4(excellent), and provide comments on each of the following sections. Finally, submit a global score with the same scale with 1-2 indicating that the proposal should not move forward, and 3-4 indicating approval of the proposal. Submit this form to the NDSC.

Title of project:

PIs of participating centers:

Reviewer:

Date of review:

Background and Significance (knowledge gaps the research is intended to fill; innovative aspects of the research plan):

Research Plan (overview of experimental design, independent and dependent variables, specific aims, hypotheses):

Methods (participants: inclusion/ exclusion and anticipated number [power calculations]; procedure and instruments to be used in data collection [attach data collection forms if available]):

Significance & Anticipated Outcomes…………………………………………………………1 2 3 4

Research Plan & Methods………………………………………………………………………1 2 3 4

Global Rating………………………………………………………………………………………1 2 3 4

BMS Peer Review Form

Comments for investigators:

Circle:

Approved

Approved with revisions

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Not Approved

<u>References</u>: **BMS Module Project Procedures SOP #608**, adapted from TBIMS Standard Operating Procedure (700g) and SCIMS Module Project Peer Review Procedures.