

Loma Linda University Behavioral Medicine Center (BMC)  
Policies and Practices Governing Research

The Loma Linda University Behavioral Medicine Center (BMC) encourages individuals to make scholarly contributions to their respective disciplines, and therefore supports internal and external investigators (e.g., faculty from LLU or other universities, students from LLU or other universities, researchers from other agencies) in conducting legal, ethical, and contextually appropriate research efforts in the BMC which seek to integrate science and practice. To this end, the BMC has adopted policies and practices governing research conducted in the BMC. The two committees which seek to ensure that policies and practices governing research are followed are the:

LLU Institutional Review Board

The LLU Institutional Review Board (IRB) follows federally established guidelines and is responsible for safeguarding the rights and welfare of human research participants/subjects. The LLU IRB is concerned with the scientific merit of a proposed research project only to the extent that poorly designed research places humans at risk. Although investigators are able to submit their research proposals to the BMC Research Committee for review, all projects requiring LLU IRB review must receive LLU IRB approval prior to receiving final approval by the BMC Research Committee (NOTE: Investigators from other institutions may be required to receive additional approval from their Institutional Review Board).

BMC Research Committee

The BMC Research Committee is responsible for assessing the contextual appropriateness of a proposed research project. The contextual appropriateness of a proposed research project is evaluated on several factors germane to the BMC, such as the potential for the project to enhance clinical services offered at the BMC, protecting patients' rights, suitability/feasibility of conducting the project at the BMC, and availability of BMC resources to complete the project. All proposed research projects must be approved by the BMC Research Committee prior to initiation. A majority vote by BMC Research Committee members is required for approval of proposals. Unless otherwise specified by the Chair of the BMC Research Committee, committee members not in attendance in the meeting in which a vote is taken forfeit their vote.

Submission of Proposals

The following steps should be followed in the preparation and submission of proposals to the BMC Research Committee:

1. Obtain/complete a "Request to Conduct Research in the Behavioral Medicine Center" form.

If you are not a BMC employee or BMC Research Committee Member, you must identify at least one BMC employee who will serve as a collaborator on the proposed research project. The specific role of the BMC collaborator(s) on the proposed research project will be mutually determined by the BMC collaborator(s) and the other investigators listed on the proposal. However, as a minimum requirement, the BMC collaborator(s) shall be given the opportunity to make a direct, substantial, and professional contribution to all scholarly products generated from the research. The BMC collaborator(s) shall take responsibility and credit for contributions made on scholarly products generated from the research in accordance with ethical guidelines.

Co-investigators are strongly encouraged to mutually agree upon the contribution each investigator will make to a project prior to initiating that project. Upon completion of the study, if there is a lack of progress towards publication within a year, the BMC would have the option of discussing with the principle investigator a right to the works of that study for possible publication.

Given that members of the BMC Research Committee are familiar with the various areas of expertise and interest of BMC employees, suggestions for potential BMC collaborators may be provided by the BMC Research Committee to external investigators. While external investigators' preferences in selecting BMC collaborator(s) will, in the vast majority of cases, be approved, the BMC Research Committee does have the option of assigning additional BMC collaborator(s) to a proposed project.

2. Submit the "Request to Conduct Research in the Behavioral Medicine Center" to the BMC Research Committee and schedule a time to make a brief oral presentation of the proposal to the committee. The committee will then review the proposal and render one of the following decisions:
  - a) APPROVED - The proposed research project has received approval by the BMC Research Committee and the appropriate Institutional Review Board. The proposed research project may be initiated.
  - b) APPROVED PENDING CHANGES - The proposal will be approved if changes recommended by the BMC Research Committee are made (e.g., receiving IRB approval, altering an aspect of the research design to alleviate problems related to the contextual appropriateness of the project).
  - c) INCOMPLETE PROPOSAL - The proposal submitted lacks information and/or documentation needed by the BMC Research Committee in order to render a decision (e.g., an adequate description of the research design). Incomplete proposals will be returned to the investigator(s) and the information and/or documentation needed by the BMC Research Committee in order to render a decision will be conveyed to the investigators.
  - d) NOT APPROVED - The proposed research project fails to meet the established requirements for Institutional Review Board approval and/or is judged by the BMC Research Committee to be contextually inappropriate. Specific reasons for denial will be provided to the investigators, and the BMC Research Committee may provide suggestions for alterations to the proposed research project that, if made, will lead to reconsideration of the appropriateness of the project.
3. If the committee decision is "APPROVED", the investigator(s) are authorized to complete the project in accordance with the proposal. If the committee decision is "APPROVED PENDING CHANGES", "INCOMPLETE PROPOSAL", or "NOT APPROVED", the investigator(s) must respond to the feedback provided by the committee and submit a revised proposal to the committee for consideration. Depending on the nature of the changes, the investigator(s) may again be asked by the committee to present the revised proposal in person.
4. Following the initiation of a project, investigator(s) are required to supply the committee with a brief, written, monthly report of the progress being made on the project. At the conclusion of the project, investigator(s) are required to submit a written summary of the results and conclusions of the project to the committee.

**Request Form to Conduct Research at Loma Linda University Behavioral Medicine Center**

1. Name: \_\_\_\_\_

2. Address: \_\_\_\_\_

3. Phone numbers: Home \_\_\_\_\_ Work: \_\_\_\_\_ Cell: \_\_\_\_\_

4. Email: \_\_\_\_\_

5. Affiliation with BMC: \_\_\_\_\_

6. In accordance with “Loma Linda University Behavioral Medicine Center (BMC): Policies and Practices Governing Research”, all external investigators (i.e., those who are not employed by the BMC or who are not members of the BMC Research Committee) must identify at least one BMC employee who will serve as a research collaborator on the proposed project.

BMC collaborator(s): \_\_\_\_\_

7. Has the project received LLU IRB approval?

YES \_\_\_\_\_ (If so, please attach)

NO \_\_\_\_\_ (If not, LLU IRB approval is needed before the project can be approved by BMC)

8. If you are a student and completing this project as part of your degree, has your proposal been approved by your research committee (i.e., dissertation, thesis, project)? YES \_\_\_ NO \_\_\_ N/A \_\_\_

9. Does the project propose to use archival data collected at the BMC? YES \_\_\_ NO \_\_\_

10. Title of project: \_\_\_\_\_

11. Please attach a description of the proposal (no more than 5 pages), which includes the rationale, timeline and dissemination plan, purpose, research question, participants, measures, intervention, and design.

*To be completed by BMC Research Committee Chair (indicate date of action taken):*

*APPROVED:* \_\_\_\_\_

*APPROVED PENDING CHANGES:* \_\_\_\_\_

*Comment:* \_\_\_\_\_

*INCOMPLETE PROPOSAL:* \_\_\_\_\_

*Comment:* \_\_\_\_\_

*NOT APPROVED:* \_\_\_\_\_

*Comment:* \_\_\_\_\_

*Signature of Chair of BMC Research Committee* \_\_\_\_\_