

PROTOCOL CHANGE FORM
BEMIDJI STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD

Please complete this form and attach revised research documents for any proposed change to your protocol, consent forms, or any supportive materials (such as advertisements, questionnaires, surveys, etc.). All changes must be highlighted. Any proposed change in protocol affecting human participants must be reviewed and approved by the IRB prior to implementation, except where an immediate change is necessary to eliminate a hazard to the participant.

Principal Investigator: _____

Telephone: _____ E-mail Address: _____

Complete Mailing Address: _____

School/College: _____ Department: _____

Project Title: _____

Approval Date: _____

THE CURRENT STATUS OF THE PROJECT IS (Check one)

_____ Project currently in progress. Number of subjects enrolled is: _____

_____ Project not yet started. No subjects enrolled

_____ Project closed to subject entry

1. Briefly describe and explain the reason for the revision or amendment and the justification for the change. Include a copy of affected protocol pages and/or consent form with specific changes highlighted.

2. Does the change affect the study or subject participation (procedures, risks, costs, etc.)? _____ Yes _____ No

Please explain:

3. Does the change affect the consent document? _____ Yes _____ No

If yes, include the revised consent form(s) with the changes highlighted, and a clean copy of the revised consent form(s).

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Signatures:

Principal Investigator Date

Student Advisor (if applicable) Date