

**INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF MONTANA-MISSOULA
AMENDMENTS TO APPROVED STUDIES**

POLICY:

In certain cases the UM IRB will consider amendments to an approved study if they do not add a vulnerable subject group or increase the risk to an approved subject group.

PROCEDURES:

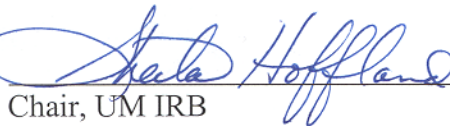
A Project Director on a currently approved study should submit a memo to the UM IRB Chair that explicitly lists the changes in the study for which approval is requested. Also, the request for amendment(s) should include new copies of documents which need revision if the amendment(s) are approved. Examples of these are Informed Consent forms, protocols, or confidentiality plans.

The UM IRB Chair will evaluate the amendment request to determine if it qualifies for expedited review. If not, it must be submitted to the entire IRB at one of its scheduled meetings.

At the discretion of the IRB Chair, a new proposal submission can be required if:

1. an amendment will substantially change the study from that which was originally approved; or
2. the incremental sum of several amendments has substantially changed the study.

APPROVED: _____


Chair, UM IRB

DATE: _____

11/12/03