UNIVERSITY OF MONTANA

INSTITUTIONAL REVIEW BOARD
for the Protection of Human Subjects in Research
FWA 00000078

Research & Development
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Rev. 06/14

AMENDMENTS TO APPROVED STUDIES
45 CFR 46.103(b)(4)(iii)

POLICY:

Any proposed changes to a previously-approved project must be reviewed and approved by the IRB before being made, unless extremely minor.

PROCEDURES:

The Principal Investigator (PI) of a currently approved study should submit an Amendment Request to the UM IRB using form RA 110 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 the checklist, recruitment flyers, Informed Consent forms, survey instruments, or confidentiality plans.

The UM IRB Chair or Coordinator will evaluate the amendment request to determine if it qualifies for the same level of review as originally determined. If the proposed amendment increases the level of risk to greater than minimum, 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.

The IRB will notify the PI of its determination by email. All correspondence and attachments must be retained by the PI. Revised informed consent forms or recruitment flyers will be date-stamped by the IRB, and the attached PDF must be used as a master from which to make copies.

The expiration date for an approved amendment will match that of the last protocol approval expiration date.