

**INSTITUTIONAL REVIEW BOARD  
THE UNIVERSITY OF MONTANA-MISSOULA**

**PROMPT REPORTING: UNANTICIPATED PROBLEMS AND SERIOUS OR  
CONTINUOUS NONCOMPLIANCE**

**POLICY:** The UM IRB will review all unanticipated adverse events in an approved study and all serious or continuing noncompliance of investigators with human subject protocols.

**PROCEDURES:**

1. The Project Director or others involved in research projects will promptly (within 5 working days of the event) report to the IRB Chair any substantial changes in activities of the project that was approved by the IRB, any unanticipated problems, unexpected events or any serious or continuing non-compliance with the study protocol.
2. The UM IRB Chair will immediately investigate the situation(s) and may take the following actions:
  - i. If the situation is severe, immediately place the study on "hold" until the UM IRB can review the information and decide on a course of action.
  - ii. Do not place the study on "hold" but refer the situation to the UM IRB for review.
  - iii. If the event posed minimal risk to the subject, deal with the matter Administratively.
3. In cases referred to the UM IRB, the IRB can:
  - i. Permanently close the study.
  - ii. Request that a revised protocol be submitted which contains modified subject eligibility requirements and/or additional safety procedures.
  - iii. Decide that the risk to the subject(s) was minimal and let the study proceed, with or without more frequent reviews.
4. All cases of serious or continuous noncompliance with study protocols will be reviewed by the UM IRB, which may:
  - i. Permanently close the study.
  - ii. Sanction the investigator(s) on all human subject research; sanctions may include suspensions for varying terms or permanent exclusion from participating in human subject research at UM.
  - iii. Institute oversight procedures (described in UM's *IRB Oversight and Verification* policy) on the study and/or all studies of the investigator(s).
  - iv. Report to the appropriate UM officials and/or federal department and agency heads.

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

Chair, UM IRB

DATE: \_\_\_\_\_

11/12/03