INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF MONTANA-MISSOULA

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. All unanticipated or adverse events occurring during approved human subject research will be reported to the UM IRB as mandated in the "Prompt Reporting" policy.

2. The UM IRB Chair will immediately investigate the situations 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 on a separate policy) on the study and/or all studies of the investigators.

APPROVED: Jan A. Ruddell DATE: May 9, 2002
Chair, UM IRB