INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF MONTANA-MISSOULA

DATA AND SAFETY MONITORING PLANS AND BOARDS

POLICY: If required by an Institute of the National Institutes of Health, the UM IRB will approve Data and Safety Monitoring Plans before approving the clinical research proposal

PROCEDURES: Preparation of each individual Monitoring Plan and recommendations for DSMB membership are the responsibility of the PI of the IRB proposal; the plan should be included with the proposal submitted to the UM IRB. Once the proposal and plan are approved by the UM IRB, the PI must submit it to the appropriate Institute's Program Scientist for approval. After the Plan is approved, the UM IRB will establish a Data Safety Monitoring Board (DSMB), following procedures in the approved Plan. The DSMB will act independently of the UM IRB to evaluate data from the study on an on-going basis to assure participant safety and study integrity. If significant safety problems or deviations are found by the DSMB, these will be reported within five (5) working days to the UM IRB and to the Institute's Program Scientist.

APPROVED: Sheila Hoffland DATE: 12/13/04
Chair, UM IRB