

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

BENEVICENCE: THE RISK-BENEFIT RATIO

POLICY: The UM IRB will consider beneficence during evaluations of research proposals involving human subjects.

PROCEDURES: The UM IRB is charged with deciding, for any proposed activity which falls under its jurisdiction, whether: "The risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept (those) risks" (Federal Register, May 30, 1974).

The assessment of the risk/benefit relation is a complex task. There are risks of injury or discomfort to the individual that can be physical, psychological and/or social. There can be potential benefits to the individual, to a group to which the individual belongs, and/or to society. In reviewing applications, the IRB must carefully assess the types and degrees of both risks and benefits for a given subject population, as well as the investigator's communication of these risks and benefits in the consent process and form.

While the IRB is not charged with reviewing scientific design per se, it must sometimes do so in order to assess risk/benefit ratio. If a study design does not seem adequate to attain the stated aim of the investigation, then no benefit can be anticipated from conducting the study, and there is no justification for placing any subject at risk, however minimal. Thus, the design of the study must be sound, and the nature and likelihood of all risks and benefits must be made clear in any application to the IRB.

APPROVED: 
Chair, UM IRB

DATE: 5/27/03