INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF MONTANA-MISSOULA

COMPONENTS OF AN IRB SUBMISSION

POLICY: In order to be considered by the UM IRB for approval, a complete package of information must be submitted for review.

PROCEDURES: The Project Director must complete the *IRB Checklist* and prepare an *IRB Summary*, which contains the following components:

1) Indicate clearly the purpose of the research project and explain why the study is being done. Generally included are literature related to the problem, hypotheses, and discussion of the problem's importance.

2) Indicate who the subjects are and note explicitly whether they include minors (under age 18, per Montana law) and/or members of physically, psychologically or socially vulnerable populations. Explain why the subjects would be considered physically, psychologically or socially vulnerable.

3) Include the procedure(s) for recruiting or selecting subjects.

4) Explain where the study will take place. If permission will be required to use any facilities, indicate those arrangements. Submission of written permission may expedite your proposal.

5) Indicate precisely and explicitly the activities the subjects will perform and how the experimental subjects will be used. Describe the instrumentation and procedures to be used and kinds of data or information to be gathered. Provide enough detail so the IRB will be able to evaluate the intrusion from the subject's perspective.

6) Discuss the benefits of the research, if any, to the human subjects and to scientific knowledge.

7) Outline the risks and discomforts, if any, to which the subjects will be exposed. Such deleterious effects may be physical, psychological, or social. Some research involves violations of normal expectations, rather than risks or discomforts; such violations, if any, should be specified.

8) Describe the means to be taken to minimize each such deleterious effect or violation.

9) Indicate the means by which the subject's personal privacy is to be protected, and the confidentiality of information maintained.

10) Include a copy of any written consent form to be signed by the subjects, if used. An informed consent form is required when a project involves more than minimal risk but may be used whenever the researcher desires. It may be helpful for the subjects to read about the experiment or project so that they are very clear as to what they are agreeing. (See the appropriate section of the *IRB Guidelines and Procedures* for the specific content of written consent forms.)

   a) A copy of the consent form should be given to all subjects, including parents/guardians of subjects less than 18 years of age.

   b) All subjects under the age of 18 must have written parental or custodial consent.

   c) Assent by child subjects. All child subjects are to be given a clear and complete picture of the research they are being asked to engage in, together with its attendant risks and benefits, as their developmental status and competence will allow them to understand. Children from the ages of 10 through 17 years must give written assent, if developmentally competent. The Child Assent form must be written at a level that can be understood by the child. Ask at the Office of Research for more information on Child Assent.

11) If a waiver of written informed consent is desired, include justification for the waiver. A waiver is necessary only if the research would normally require written informed consent because it involves some risk or a vulnerable population.

Attach a copy of any cover letter to accompany a survey.

APPROVED: _____ DATE: 5/27/03

Chair, UM IRB