INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF MONTANA-MISSOULA

APPROVAL: EXEMPT, ADMINISTRATIVE, BOARD

POLICY: The University of Montana requires that all research projects involving human subjects be approved by UM's IRB. Any employee, adjunct faculty member or student who, on behalf of The University of Montana, conducts research using human subjects must receive IRB approval prior to recruiting or screening, and the necessary forms must be submitted prior to the research proposal being submitted to a sponsor for funding.

PROCEDURES:

1. Unless otherwise noted, IRB approval is granted for one year.

2. To obtain exempt status, paperwork must be submitted to the IRB for review and decision.

   Research Exempt from Review status (Exempt status) is granted by the IRB Chair to proposals which do not involve research subjects from statutorily vulnerable populations, or do not involve more than minimal risk:

   (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   - (i) research on regular and special education instructional strategies, or
   - (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

   (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

   - (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   - (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

   (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:

   - (i) the human subjects are elected or appointed public officials or candidates for public office; or
   - (ii) federal statute(s) require(s) without exception that the confidentiality of the

personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
(i) public benefit or service programs;
(ii) procedures for obtaining benefits or services under those programs;
(iii) possible changes in or alternatives to those programs or procedures; or
(iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

3. The IRB Chair may, at the Chair's discretion, administratively approve the project without convening the full Board. If Chair is unable to determine if expedited review is warranted, the Chair may seek another opinion either from another current IRB member or from an expert in the research area under consideration. If the IRB Chair does not concur that expedited review is warranted, the Chair will ask the Project Director to revise the IRB Checklist and submit an IRB Summary for full IRB review.

4. Expedited (Administrative) Approval may be granted by the IRB Chair to proposals which fail to meet the criteria for Exempt Status and if:

a. The subjects are not from a statutorily vulnerable population and the research involves either minimal risk or no foreseeable risk to them.

b. The project involves minimal or no risk. Minimal or no-risk projects are those which involve no foreseeable danger to the subjects. Examples of no-risk procedures include: administration of anonymous opinion questionnaires, measurements such as reaction time or hand-eye coordination, and interviews on non-threatening topics.

Full IRB Review will be necessary when the project involves a population that is physically, psychologically or socially vulnerable or involves more than minimal risk to the human subjects; and, as such, written informed consent is required of the subjects.

The IRB Chair shall present the IRB Checklist and IRB Summary to the IRB at its next meeting. The project director may be asked to attend this meeting as a source of additional information.

Possible IRB Actions

a. Designate the research as exempt from IRB review.

b. Approve the research. The research may involve some risk to subjects, but the IRB does not consider the risk to be unreasonable and/or the researcher has taken all practical steps to minimize the risk.

c. Conditionally approve the research. This approval is for minor corrections to the proposal. Once the conditions have been met and approved by the IRB Chair, the researcher may proceed with the project. Conditions might include revising the consent form to more clearly explain the procedure; adding a foreign language version of the consent form; receiving appropriate clearance from a particular agency or department, such as the Student Health Service; or discontinuing the research if deleterious effects occur.

WHAT FACTORS MAKE CONDITIONAL APPROVAL MANDATORY?

The Chair submits to the Project Director the list of conditions that must be satisfied. The Project Director submits documentation that the conditions have been satisfied. Upon review, the Chair may either approve the documentation by signing and dating the document, or return the documentation to the Project Director for additional changes.

Conditional Approval proposals will not be granted final approval until all conditions have been satisfied. Data collection may not begin until final approval has been granted.

Ask for resubmission of the Proposal. If the proposal does not contain enough information for the IRB to make an informed judgment or when it feels the research design contains clear dangers and should be revised to reduce the risk of harm to human subjects, the Project Director can be asked to resubmit the proposal or submit new information.

Disapprove the research. If the proposed research does not adequately protect the subjects, the IRB chair or IRB may disapprove the proposal. Reasons for the disapproval will be given to the Project Director.

APPROVED: Sheila Hoffland DATE: 11/12/03
Chair, UM IRB