Rev. 8/99

INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF MONTANA-MISSOULA

CHECKLISTS FOR UM IRB

POLICY: Checklists must be completed and submitted to the UM IRB for each new project application or for annual continuations continuation of an approved project.

PROCEDURES: All new proposals for research involving human subjects that are submitted ti the UM IRB must have a completed **Checklist** (form RA-108) attached; continuation projects must have a completed form RA-109 attached. Examples are attached to this Policy.

APPROVED: _____ DATE: 10/14/99
Chair, UM IRB

Form RA-108
(Rev. 6/08)

IRB use only

Protocol No:
Approval Date:
Expiration Date:
Amended:

THE UNIVERSITY OF MONTANA-MISSOULA
INSTITUTIONAL REVIEW BOARD (IRB)
CHECKLIST / APPLICATION
(Use for Human Subject Research)

At The University of Montana (UM), the Institutional Review Board (IRB) is the institutional review body responsible for oversight of all research activities involving human subjects outlined in the U.S. Department of Health and Human Services Office of Human Research Protection (www.hhs.gov/ohrp) and the National Institutes of Health, Inclusion of Children Policy Implementation (http://grants.nih.gov/grants/funding/children/children.htm).

Instructions: A separate registration form must be submitted for each project. IRB proposals are approved for three years and must be continued annually. **Faculty members** may email the completed form as a Word document to the IRB at *(IRB@umontana.edu).* **Students** must submit a hardcopy of the completed form to IRB administrator, Colleen Hoffman at The Office of the Vice President for Research & Development located in University Hall 116.

1. Administrative Information

Project Title:	
Principal Investigator:	Title:
Email address:	
Work Phone:	Cell Phone:
Department:	Office location:

2. Human Subjects Protection Training *(All investigators, including faculty supervisors, on this project must complete the self-study course on protection of human research subjects, available at the UM IRB website: www.umt.edu/research/irb.htm)*

NAME	PI	CO-PI	Faculty Supervisor	Research Assistant	DATE COMPLETED HUMAN SUBJECTS PROTECTION COURSE
	☐	☐	☐	☐	
	☐	☐	☐	☐	
	☐	☐	☐	☐	
	☐	☐	☐	☐	
	☐	☐	☐	☐	
	☐	☐	☐	☐	

3. Project Funding

Is grant application currently under review at grant funding agency? ☐Yes ☐No			**Has grant proposal received approval and funding? ☐Yes ☐No**	
Agency	**Grant No.**	**Start Date**	**End Date**	**PI**
Is this part of your thesis or dissertation?		**If yes, date you successfully presented your proposal to your committee:**		

For IRB Use Only

IRB Determination:

_____ Approved Exemption from Review Exemption # _____
_____ Approved by Expedited/Administrative Review
_____ Full IRB Determination
  _____ Approved
  _____ Conditional Approval *(see attached memo)*
  _____ Resubmit Proposal *(see attached memo)*
  _____ Disapproved *(see attached memo)*

Signature IRB Chair: _____ Date: _____

4. Purpose of the Research Project (not to exceed 500 words): Briefly summarize the overall intent of the study. Your target audience is a non-researcher. Include in your description a statement of the objectives and the potential benefit to the study subjects and/or the advancement of your field. Generally included are literature related to the problem, hypotheses, and discussion of the problem's importance.

5. Subject Information:

a. Human Subjects *(identify, include age/gender)*:

b. Are any of the following included?

Minors included *(under age 18, per Montana law)*? ☐ Yes ☐ No

If yes, specify age range: to

Members of a physically, psychologically or socially vulnerable population? ☐ Yes ☐ No

If yes, please explain why the subjects would be considered physically, psychologically or socially vulnerable:

c. How are subjects selected or recruited? (attach copies of all flyers, advertisements, etc. that will be used in the recruitment process; these require UM IRB approval):

d. How many subjects will be included in the study?

e. How will subjects be identified in your work papers and in your publications: *(check one):*

☐ Identified by name and/or address or other

☐ Confidentiality Plan

☐ Never know participant's identity

f. Describe the means by which the human subject's personal privacy is to be protected, and the confidentiality of information maintained. If you are using a Confidentiality Plan (as checked above) include in your description a plan for the destruction of the confidential materials.

6. Information to be Compiled

a. Explain where the study will take place *(physical location not geographic. If permission will be required to use any facilities, indicate those arrangements and attach copies of written permission):*

b. Subject matter or kind(s) of information to be compiled from/about subjects:

c. Activities the subjects will perform and how the 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:

d. Is information on any of the following included? *(check all that apply)*:

- ☐ Sexual behavior
- ☐ Drug use/abuse
- ☐ Alcohol use/abuse
- ☐ Illegal conduct
- ☐ Information about the subject that, if it became know outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability.

e. Means of obtaining the information *(check all that apply)*:

- ☐ Field/Laboratory observation
- ☐ In-person interviews/survey *(attach questionnaire/instrument)*
- ☐ Tissue/Blood sampling
- ☐ Telephone interviews/survey *(attach questionnaire/instrument)*
- ☐ Measurement of motions/actions
- ☐ On-site survey *(attach questionnaire/instrument)*
- ☐ Use of standard educational tests, etc.
- ☐ Examine public documents, records, data, etc.
- ☐ Mail survey *(attach questionnaire/instrument)*
- ☐ Examine private documents, records, data, etc.
- ☐ Medical records *(require HIPAA form)*
- ☐ Other means *(specify)*:

f. Will subjects be *(check all that apply)*:

☐ Videotaped ☐ Audio-taped: ☐ Photographed

Explain how data will be used, how data will be destroyed, and who will transcribe:

g. Discuss the benefits of the research, if any, to the human subjects and to scientific knowledge *(if the subjects will not benefit from their participation, so state)*:

h. Outline the risks and discomforts, if any, to which the human subjects will be exposed *(such deleterious effects may be physical, psychological, professional, financial, legal, spiritual, or cultural. Some research involves violations of normal expectations, rather than risks or discomforts; such violations, if any, should be specified)*:

i. Describe the means to be taken to minimize each such deleterious effect or violation:

7. Consent

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. *(Templates and examples of Informed Consent Forms are available at* http://www.umt.edu/research/irb/irbforms.htm *).*

- A copy of the consent form must be offered to all subjects, including parents/guardians of subjects less than 18 years of age (minors).
- All minor subjects must have written parental or custodial permission.
- Assent by minor subjects. All minor 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.
- All minors from 10 to 18 years of age are required to give written assent. Minors less than 10 years of age and all individuals, regardless of age, with delayed cognitive functioning (or with communication skills that make expressive responses unreliable) will be denied involvement in any research that does not provide a benefit/risk advantage. Good faith efforts will be made to assess the actual level of competence of minor subjects where it is in doubt. The Minor Assent Form must be written at a level that can be understood by the minor.

a. Is a written consent form being used? ☐ YES *(attach copy)* ☐ NO
Is a written parental permission form being used? ☐ YES *(attach copy)* ☐ NO
Is a written minor assent form being used? ☐ YES *(attach copy)* ☐ NO

b. Will subject(s) receive an explanation of the research before and/or after the project?
☐ YES *(attach copy)* ☐ NO

c. If a waiver of written informed consent is desired, describe your justification for the waiver *(a waiver is necessary only if the research would normally require written informed consent because it involves some risks or a vulnerable population)*:

The principal investigator agrees to comply with all requirements of The University of Montana-Missoula IRB, the U.S. Department of Health and Human Services Office of Human Research Protection Guidelines, and NIH Guidelines and further agrees to ensure all members of the Principal Investigator's team are familiar with the requirements and risks of this project, as well as, complete the Human Subject Protection Course available at http://www.umt.edu/research/irb/irboverview.htm.

Principal Investigator's Statement

I certify that the statements made in this request are accurate and complete. I also agree to the following:

- If I receive approval for this research project, I agree to inform the IRB in writing of any emergent problems. I further agree not to proceed with the project until the problems have been resolved.
- I will not make any significant procedural changes to procedures involving human subjects without submitting a written amendment to the IRB and will not undertake such changes until the IRB has reviewed and approved them.
- It is my responsibility to ensure that every person working with the human subjects is appropriately trained.
- I will not begin work on the procedures described in this protocol until I receive notice of approval from the IRB.
- I will keep a copy of this protocol (including all consent forms, questionnaires, and recruitment flyers) and all subsequent correspondence.

Signature of Principal Investigator: _____ Date: _____

Note: I AM AWARE THAT ELECTRONIC SUBMISSION OF THIS FORM FROM MY COMPUTER CONSTITUTES MY SIGNATURE.

Students Only (students must submit hardcopy of IRB application complete with original signature of faculty supervisor)

Faculty Supervisor Signature: _____ Date: _____

Phone:_____ Email:_____

(My signature confirms that I have read the IRB Application and attachments and agree that it accurately represents the planned research and that I will supervise this research project).

For Internal Use Only

PROPOSAL # _____
Form RA-109 (Rev. 11/03)

The University of Montana

Institutional Review Board (IRB)

Continuation Report for Human Subject Research

This report must be completed if data collection and/or analysis will still be in progress one year past last IRB approval.

The Institutional Review Board (IRB) is required by Title 21, Code of Federal Regulations (Part 56.109) and Title 45, Code of Federal Regulations (Part 46.109) to conduct continuing review of ongoing projects at least once per year

Project Director: _____ Dept.: _____

Signature: _____ Phone Number: _____

E-mail Address: _____

Faculty Supervisor: _____ Dept.: _____

Signature: _____ Phone Number: _____

Name of project: _____

Date of last approval: _____

1. Approximately how many subjects have you tested? _____
2. Describe any adverse effects or unanticipated problems involving risks to subjects: _____
3. Describe the circumstances surrounding the withdrawal of any subjects from this research: _____
4. Describe any complaints received from subjects about the research: _____
5. Summarize below any recent findings or publications regarding risks or adverse effects associated with research like yours:
6. If there are any changes you wish to make to your current consent form(s) or to the originally approved study, attach a memorandum of amendment and/or a new consent form. If not, **attach clean copies of original consent form(s) for current approval stamp.**
7. Have all investigators on this project taken the self-study course on experimentation with human subjects? _____

IRB Determination For IRB Use Only

____ Exempt from Review
____ Approved by Administrative Review
____ Full IRB Determination:
- ____ Approved
- ____ Conditional Approval (see attached memo)
- ____ Resubmit Proposal (see attached memo)
- ____ Disapproved (see attached memo)

Signature / IRB Chair _____ Date: _____