APPENDIX H
Research Involving Human Subjects

“An institutional review board (IRB), also known as an independent ethics committee (IEC) or ethical review board (ERB), is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects.” (From Wikipedia, Institutional Review Board, accessed 14 SEP 2011)

Purpose
Research or experimentation that directly uses human subjects in any way must be reviewed and approved by the University of Montana Institutional Review Board (IRB). The purpose of this document is to outline the process for obtaining IRB approval prior to conducting research on human subjects.

Background
It is federally mandated that all research using human subjects, including any use of personal data, be formally reviewed by an IRB. Montana Tech has an appointed, voluntary position that acts as the IRB point person on campus and who will carry forward requests to conduct research using human subjects to the University of Montana’s IRB. That position is currently filled by Scott Risser. You are encouraged to contact Professor Risser early in the process to ensure that you satisfy all of the requirements. The final approval for research using human subjects is granted by the U of M IRB committee.

I. Institutional Review Board Application Process
A. The undergraduate student researcher and the mentor have the responsibility of obtaining timely approval from the IRB. The first step is to fill out Form RA-108, available from the University of Montana website (http://www.umt.edu/research/complianceinfo/IRB/) under forms.
B. The undergraduate student researcher and the mentor are required to complete one of the several on-line tutorials available from the University of Montana website (http://www.umt.edu/research/complianceinfo/IRB/). These tutorials take between 30 minutes to an hour to complete, so plan accordingly. Pay close attention to the documentation requirements for each of these courses so that you have evidence of completion.
C. There are several resources on the IRB website that can help with the completion of the IRB application. There are sample consent forms that can be modified to fit the type of research being done. There is also a reference for testing the reading level of the consent form or any educational materials formulated in relation to the research being conducted.
D. When all of the elements required for the application for IRB approval have been assembled, the packet should be emailed to Scott Risser the IRB representative at Montana Tech (srisser@mtech.edu).
E. IRB applications containing errors, deficiencies or incomplete information may be returned to the researcher for corrections. The IRB application will be reviewed a maximum of three times. If the application is still unsatisfactory after the third revision, the IRB representative reserves the right to deny approval of the proposed research.

II. Student Researcher Responsibilities
A. It is the responsibility of the undergraduate student researcher and the mentor to obtain IRB approval for any research involving human subjects or their personal data including surveys.
B. The undergraduate student researcher and the mentor need to make sure that all the information that is required in the IRB form is completed. Correct grammar and spelling is a requirement.
C. Corrections and comments given by the Montana Tech IRB representative need to be incorporated into any revised IRB applications.
D. The undergraduate student researcher and the faculty mentor are encouraged to contact the Montana Tech IRB representative if they have questions regarding the revisions suggested or about the application.

E. It is the responsibility of the undergraduate student researcher and the mentor to inform the IRB of any changes, significant events or adverse incidents that occur during the research.

III. Mentor Responsibilities
A. The mentor has the responsibility of reviewing the IRB application to ensure that the form is properly filled out. Proper grammar, spelling and clear answers on the application form will help facilitate the IRB review process.

B. The mentor needs to facilitate communication between the student, the URP committee, and the IRB if there are issues that need to be addressed.

IV. Montana Tech IRB Representative Responsibilities
A. The IRB Representative has the responsibility of reviewing IRB applications in a timely manner. Generally, feedback will be provided to the researcher within one week of receipt of the application. It might take longer if the application is submitted during scheduled breaks or if the IRB representative is out on business.

B. Corrections and suggestions will be communicated to the undergraduate student researcher and mentor via email, unless otherwise specified by the undergraduate student researcher and mentor.

C. Once the final corrections are complete, the undergraduate student researcher will need to submit a hard copy of the IRB forms with the corresponding signature that is required on the form. It can be sent through intercampus mail addressed to Scott Risser the IRB Representative at Montana Tech.

D. If the document is accurate and complete, the IRB representative will mail it to the University of Montana IRB.

E. The University of Montana IRB will directly contact the undergraduate student researcher and mentor, usually via email provided in the application, for any questions, further comments or revisions and for approval.

F. IRB approval must be received before starting any part of the research that involves human subjects. IRB approval is usually good for one year. If the undergraduate student researcher and mentor anticipate that the research is going to take longer than one year, an application for an extension must be submitted to the IRB prior to the expiration of the current approval.

G. Any violation of these rules can result in immediate termination of all research activities.

H. The IRB has the responsibility of reporting any violation in the ethical conduct of human research to the federal government.

I. The IRB reserves the right to deny approval to researchers who fail to follow IRB guidelines. IRB policies and procedures can be viewed at http://www.umt.edu/research/complianceinfo/IRB/.

J. Institutional Review Board Representative at Montana Tech:
   Scott Risser
   Liberal Studies
   Main Hall Rm. 102
   Email: srisser@mtech.edu
   Office: 406-496-4845

V. Undergraduate Research Committee Responsibilities
   The Undergraduate Research Committee will not award funding to research conducted on human subjects without proof of IRB approval.