MONTANA TECH UNDERGRADUATE RESEARCH PROGRAM

APPENDIX H Research Involving Human Subjects

Montana Tech participates in the University of Montana's (UM) Institutional Review Board (IRB) for human subject research The mission of the UM IRB, is to ensure the protection of human participants in research, maintain federal regulatory compliance, and facilitate research at UM and its affiliates, including Montana Tech.

Purpose

All projects involving human subjects research, must be approved in advance, by the IRB when Montana Tech faculty, staff, or students are engaged in the research. The purpose of this document is to outline the process for obtaining IRB approval prior to conducting research on human subjects.

Background

Montana Tech requires that all research projects involving human subjects conducted by Montana Tech faculty, staff and students be approved by UM's IRB unless the project does not qualify as "human subjects research." Any employee, adjunct faculty member, or student who, on behalf of the Montana Tech, conducts research using human subjects must receive IRB approval prior to recruiting or screening human subjects, and the necessary forms must be submitted prior to the research proposal being submitted to a sponsor for funding. IRB approval is granted for a maximum of one year, unless otherwise noted. One member of the UM IRB serves as a liaison to Montana Tech. This member can answer questions, facilitate applications, designate research as "not human subjects research," and approve exempt studies. The current Montana Tech IRB member is SD Risser (406-496-4845, srisser@mtech.edu).

I. <u>Institutional Review Board Application Process</u>

- 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 UM website (http://www.umt.edu/research/compliance/IRB/forms.php).
- B. As federally mandated and required by the UM IRB, all researchers and individuals involved in project activity must complete a course in human subject protection. This requirement may be satisfied by taking one of three courses, available on line, within the last three years. The three acceptable courses can be found here:

 http://www.umt.edu/research/compliance/IRB/hspcourse.php.
- C. There are several resources on the IRB website that can help with the completion of the IRB application (http://www.umt.edu/research/compliance/IRB/aguide.php). 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 the current Montana Tech IRB member (srisser@mtech.edu).
- E. Please note that the IRB application process may require several revisions prior to approval. These revisions are primarily to ensure the protection of human subjects, as well as federal compliance.

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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 and all changes, significant events or adverse incidents that occur during the research as per federal regulations (http://www.umt.edu/research/compliance/IRB/guidelines.php).

III. Mentor Responsibilities

- A. The mentor is the responsible investigator, and must be listed as such on the IRB application. The mentor has the responsibility of reviewing the IRB application to ensure that complete and accurate information is supplied. Proper grammar, spelling and clear language on the application will help facilitate the IRB review process.
- B. The mentor needs to facilitate communication between the student, the URP committee, and the UM 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. For review timeline information, please see http://www.umt.edu/research/compliance/IRB/aguide.php.
- B. The UM IRB will contact the undergraduate student researcher and mentor, usually via email provided in the application, for any questions, further comments or revisions and for approval.
- C. 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.
- D. Any violation of these rules can result in immediate termination of all research activities.
- E. The IRB has the responsibility of reporting any violation in the ethical conduct of human research to the federal government.
- F. 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/.
- G. Institutional Review Board Representative at Montana Tech:

SD Risser

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 IRB approval.