**NORTHWEST MISSOURI STATE UNIVERSITY**

**INSTITUTIONAL REVIEW BOARD (IRB)**

The IRB safeguards the rights and welfare of human participants. It ascertains the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB reviews and has authority to approve, require modification in (to secure approval), or disapprove all research activities covered by the Code of Federal Regulations, Title 45 Public Welfare, Part 46 Protection of Human Subjects as decreed by the Department of Health and Human Services, National Institutes of Health, and Office for Protection from Research Risks.

IRB Membership will include at least five members with varying backgrounds to promote complete and adequate review of research activities involving human participants commonly conducted by the institution. Membership will include at least one member whose primary concerns are in scientific areas and at least one member who primary concerns are in nonscientific areas. Membership shall also include at least one member who is not otherwise affiliated with the institution and whose is not part o the immediate family of a person who is affiliated with the institution.

The IRB will consider three types of proposals: Exempt, Expedited, and Full Review. It shall require adequate informed consent given to participants. The IRB shall notify investigators of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If research activity is disapproved, written notification of the reasons for the decision shall be provided to the investigator who will have an opportunity to respond in person or in writing. The IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than one per year, and shall have authority to observe or have a third party observe the consent process and the research.

In order to approve research, the IRB shall determine the following requirements are satisfied:

* Risks to participants are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
* Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.
* Selection of participants is equitable.
* Informed consent will be sought form each prospective participant or the participant’s legally authorized representative.
* Informed consent will be appropriately documented.
* When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
* When appropriate, there are adequate provisions to protect the privacy of participants and maintain the confidentiality of data.
* When some or all participants are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, mentally disabled persons, or economically disadvantaged persons), additional safeguards must be included in the study to protect the rights and welfare of these participants.

IRB approval shall be suspended or terminated if research activities are not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to participants. A written statement of the reasons for the IRB’s action shall be reported promptly to the investigator and the appropriate institutional officials.

The IRB shall maintain adequate documentation for a period of three years of IRB activities including:

* Copies of all research proposals, approved consent documents, progress reports from investigators, and reports of injuries to participants.
* Minutes of IRB meetings that include attendance; actions taken by the IRB; the vote on these actions including number of members voting for, against, or abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
* Records of continuing review activities.
* Copies of all correspondence between the IRB and the investigators.
* A list of IRB members.
* Written procedures for the IRB.
* Statements of significant new findings provided to participants.

\_\_\_\_\_\_\_\_\_\_\_\_\_

Information taken from the Department of Health and Human Services 45 CFR Sub-part A. Effective August 19, 1991. Available <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>