

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Full Review

Research proposals must be submitted a minimum of two (2) weeks prior to the scheduled meeting in order to receive full review. The dates of the scheduled meetings will be kept on file at the Office of Compliance and on the IRB website (www.mtsu.edu/irb). **Research protocols will not be approved by the IRB until all policies and procedures have been followed. The IRB will not give “after-the-fact” approval on research involving human subjects.**

Written documentation of legally effective informed consent is required for all research involving subjects who have been determined to be "at risk." Research on minors or subjects incompetent to give consent requires permission by a parent or legal guardian. Deception research will only be approved if it meets certain conditions (e.g. debriefing).

Examples of research that would require full review include:

- Research which might put subjects at risk
- Non curricular, interactive research in schools
- Research involving deception that might have adverse effects on the subjects
- Interviews or surveys on sensitive topics
- Research on vulnerable populations; e.g. minors (*except as listed above in expedited review*), prisoners, pregnant females, and the mentally incompetent
- Research conducted outside the United States, unless it is innocuous in nature. International research will not be approved as exempt but can fall under expedited review.

If you believe your project will be reviewed by the Full IRB Committee, download and complete the “IRB application for Full or Expedited Review” from the Forms page. Submit all documents to compliance@mtsu.edu.

6.1.3.1 Full Review Process

IRB Review Responsibilities – The IRB shall have the responsibility to review and authority to approve, require modification to, table, or disapprove all research activities. Each board member will study the protocol under review to ensure that no unnecessary or unacceptable hazards are present and that adequate safeguards are provided for the research subjects. IRB members shall have all access to all documents relating to the research protocol, including all information provided by the principal investigator.

Presenting at the IRB Meeting – At the IRB meeting, the Principal Investigator or coinvestigator may be asked to explain the purpose for, risks of, and alternatives to the proposed research, including subject selection and the exclusion criteria. IRB members are encouraged to ask clarifying questions concerning the protocol and consent process.

IRB Action – IRB members then discuss the case and make determinations regarding the category of risk, risk and benefit issues, and whether informed consent procedures are adequate. The IRB then votes and takes one of the following actions.

Approved – The IRB shall provide written notice to the Principal Investigator. After receiving this notice, the Principal Investigator may begin research. In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

- Risks to subjects are minimized:
 - By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk,
 - And whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Populations should not be exploited nor underrepresented.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Approval Subject to Modification – The IRB shall provide written notice to the Principal Investigator of its approval subject to modification, identifying the specific areas of modification requires. The Principal Investigator must provide the IRB with additional information, revised documents, and/or informed consent document incorporating the modifications. The IRB Chair(s) or designated member of the IRB shall review the revised protocol and/or informed consent document. The reviewer will then provide written notice of approval of the protocol if the required modifications have been made.

Tabled – The IRB required additional information and/or has a concern regarding the proposed research project. The Principal Investigator will be notified of the IRB's decision and will be scheduled to address the issues in question at the next IRB meeting.

Disapproval – If the IRB disapproves a research protocol, the IRB shall provide to the Principal Investigator, in writing, the reasons for the IRB decision and an opportunity for the Principal Investigator to appeal the decision. However, it is the policy of the IRB to not disapprove research but to work with the investigator so that they can obtain approval of their research protocol.