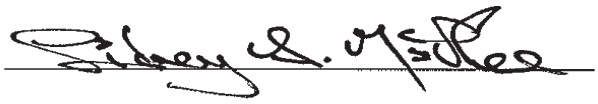
MIDDLE TENNESSEE STATE UNIVERSITY

POLICIES AND PROCEDURES MANUAL

POLICY NO: I:01:24 **DATE: February 13, 2012**

SUPERSEDES POLICY NO: I:01:24 **DATED: January 19, 2012**

SUBJECT: Protection of Human Subjects in Research

APPROVED: Sidney McPhee, President 

I. COMPLIANCE WITH FEDERAL CODE

Middle Tennessee State University (MTSU) adopts and continues its policy that all research activities involving human subjects conducted at MTSU shall be conducted in accordance with current federal regulations. Current federal regulations and guidelines include but are not limited to the "The Common Rule" (45 Code of Federal Regulations (CFR) Part 46) established by the Office of Human Research Protections, 21 CFR 50, 312, 812 as established by the Food and Drug Administration, and the "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (April 18, 1979). The University's commitment to this policy shall be specified in the Federal Wide Assurance Agreement on file with the Office of Human Research Protections.

II. COMPLIANCE POLICY

In furtherance of this policy ,the University shall establish an Institutional Review Board (IRB) whose members shall be appointed by the Vice Provost for Research/Dean of the College of Graduate Studies (VPR/Dean). The IRB shall perform the functions and be composed in the manner set forth in MTSU Policy No. I:01:02, University Standing Committees. At the discretion of the VPR/Dean, and in consultation with the Compliance Officer, IRB members shall be appointed to evaluate and approve research involving human subjects. The IRB committee shall consist of at least five (5) members with

diverse backgrounds and expertise, at least one of whom represents the community and is not affiliated with the University.

III. DEFINITIONS

Assent – an individual's affirmative agreement to participate in research obtained in conjunction with permission from the individual's parents or legally authorized representative. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Assurance - a contract or agreement that establishes standards for human subjects research as approved by the Office for Human Research Protections (OHRP).

Beneficence - to do no harm and maximize possible benefits and minimize possible harms.

Children - persons who have not attained the legal age for consent in the jurisdiction in which the research will be conducted.

Cognitively Impaired - having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorder), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including individuals under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and individuals with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interest.

Dissent – an individual's negative expressions, verbal and/or non-verbal, that they object to participation in the research or research activities.

Human subject - a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information

Identifiable private information - information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Informed Consent - assures that prospective human subjects will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. Informed consent is an ongoing process.

Justice - fairness in distribution or that benefits and burdens are distributed equally.

Legal Guardian – an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Legally Authorized Representative - an individual, judicial, or other body authorized under applicable law to grant permission on behalf of a prospective participant for participation in research activities.

Minimal Risk - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. An example of minimal risk is the risk of drawing

a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).

Prisoner - any individual involuntarily confined or detained in a penal institution, including individuals detained in other facilities which provide alternatives to criminal prosecution or incarceration, and individuals detained pending arraignment, trial, or sentencing.

Quorum - the majority of the members of the IRB needed to vote.

Research - a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purposes of the policy, whether or not they are supported under a program which is considered research for other purposes.

Respect for Persons or Autonomy - individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.

Vulnerable Population - includes children, prisoners, and pregnant women, fetuses, and neonates.

IV. OFFICERS

A. Chairperson

The Chairperson shall be elected annually from and by the IRB membership at the last meeting of the academic year. The Chairperson shall:

- Preside at all meetings or designate a member to serve in his/her absence.
- Prepare and distribute a tentative agenda to IRB members at least three working days prior to the meeting.
- Call special meetings and appoint ad hoc subcommittees when necessary.
- Assume responsibility for the preparation of the annual report to the VPR/Dean.
- Assume responsibility of execution of IRB policies.

B. Vice-Chairperson

The Vice-chairperson shall be elected annually from and by the IRB membership at the last meeting of the academic year. The Vice-chairperson shall:

- Take on all of the aforesaid responsibilities of the Chairperson should the Chairperson not be available.

C. Institutional Official

As a non-voting member of the Committee, the Institutional Official shall be the VPR/Dean and shall be appointed by the President of the University in accordance with approved procedure for making such appointments. The Institutional Official shall:

- Serve as the Institutional Official for the Committee and as the liaison between the University, Committee, and Office of Research Integrity, and Office of Human Research Protections.
- Provide an annual report to the Office of Research Integrity, describing the activities of the Committee including any changes in membership, dates of non-compliance, and dates evaluations were submitted to his/her office.

D. Compliance Officer

The Compliance Officer shall:

- Call special meetings and appoint ad hoc subcommittees when necessary.
- Assist with the preparation of the agenda.
- Record the minutes of all IRB Meetings.
- Prepare the annual report for the VPR/Dean.

V. MEETINGS AND ATTENDANCE

A. Meetings

1. There shall be a minimum of two meetings of the IRB each semester. Meeting schedules will be posted on the IRB Web Page. Special meetings may be called by the Chairperson as deemed necessary for the performance of IRB responsibilities.
2. Meeting agendas and protocol applications shall be made available to members for review 14 days prior to scheduled meetings.
3. The meeting agenda shall be approved at the beginning of each meeting.
4. A simple majority of the membership shall constitute a quorum.

B. Attendance

1. Attendance of members at IRB meetings is expected and required. If a member must be absent, notice should be given to the Chairperson or Secretary as soon as it is known.
2. To maintain quorum, the non-scientist must be present. If the non-scientist member cannot be present, the meeting will have to be postponed until a quorum can be obtained.
3. If there is research involving one of the vulnerable populations covered under the Common Rule, i.e. children, prisoners, and/or pregnant women, fetuses, neonates, then the expert for that specific population must be present as well.

Absence from fifty percent (50%) of regular meetings without due cause will result in a request by the IRB chairperson to the Institutional Official for replacement of that member.

VI. REVIEW PROCEDURES

All investigators who plan to participate in research activities involving human subjects must submit the Human Subjects Review Form to the Office of Compliance for review and approval. If the activity involves a proposal to an outside agency, the review form and proposals must be submitted to the IRB before the proposal is mailed to the sponsoring agency. The review form can be downloaded into Microsoft Word from the IRB Web Page www.mtsu.edu/irb.

The Office of Compliance shall determine what type of review for which the research qualifies. Research proposals must be submitted a minimum of two weeks prior to the scheduled IRB meeting in order to receive full review. The dates of the scheduled meetings will be kept on file in the Office of Compliance and on the IRB Web Page. Review forms not received by the deadline date will not be reviewed until the following meeting. There is no deadline for submitting research proposals for either exempt or expedited review.

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.

Please see the Comprehensive Policies and Procedures for the IRB online www.mtsu.edu/irb or in the Office of Compliance for further reference.

VII. INFORMED CONSENT

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

Please see the Comprehensive Policies and Procedures for the IRB online www.mtsu.edu/irb or in the Office of Compliance for further reference.

VIII. PROJECT CATEGORIES

Once it has been determined that an activity is to be considered human subjects research, it will be reviewed under one of three categories: exempt review, expedited review, and full review. Each researcher should make the initial determination regarding the appropriate category of review, although the IRB or its designee may require review under another category. The researcher can always request a higher level of review than that required.

The project categories, along with examples of the types of projects included in each category, are listed below.

Project Category I (Exempt Review)

Exempt status does NOT mean the study is exempt from IRB review. Exempt is defined as being exempt from further review and approval beyond the Compliance Officer or either the IRB Chair or Vice-Chair. Research using data from living persons does not require IRB approval when the research does not involve human subjects as defined in 45CFR46, i.e. obtaining research data through intervention or interaction with an individual or with their identifiable private information; or the only involvement of human subjects is one of the "exempt" categories. On October 30, 2007, the IRB ruled that cognitive psychological tests can fall under Exempt Category 2 of the Common Rule as long as the tests are innocuous in nature and confidential. The Compliance Officer, IRB member, and/or Chair retains the discretion to determine if the study falls under another type of review.

Project Category II (Expedited Review)

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the "expedited" categories may be reviewed by the IRB through the expedited review. The categories in the list apply regardless of age of subjects, **except as noted**. This research generally does not require written documentation of informed consent, but oral consent is required for all research involving direct interaction with subjects. All research in schools requires written permission from the school district in addition to the principal of each school. Minor changes in approved research is also covered under expedited review.

Project Category III (Full Review) 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

1. Research which might put subjects at risk
2. Research involving psychological or physiological intervention
3. Non curricular, interactive research in schools
4. Research involving deception that might have adverse effects on the subjects
5. Interviews or surveys on sensitive topics
6. Research on special populations; e.g. minors *(except as listed in expedited review)*, prisoners, and the mentally incompetent
7. Research conducted outside the United States if it involves one or more of the above examples.

The IRB may require full review of any research submitted or approved under expedited review. Human Subjects Research forms can be downloaded from the IRB Web Page (www.mtsu.edu/irb).

Please see the Comprehensive Policies and Procedures for the IRB online www.mtsu.edu/irb or in the Office of Compliance for further reference.

Continuing Review of Ongoing Projects

The research investigator is solely responsible for the timely submission of continuing review materials. The investigator must submit a letter requesting continued review along with a Progress Report. The Progress Report form can be found at the following website: http://www.mtsu.edu/irb/irb_forms.shtml. **The IRB will not give "after-the-fact" approval for continued review**. A renewal request and Progress Report must be submitted prior to the expiration date.

The following factors are taken into consideration when determining the appropriate review interval and may require to be reviewed more often than annually, these factors, are but are not limited to:

1. There have been confirmed instances of serious adverse events or non-compliance;
2. Involvement of vulnerable populations;
3. Research conducted internationally;
4. Involvement of recombinant DNA or other types of gene transfer protocols;
5. Use of waiver of informed consent procedures, (e.g. surrogate consent);
6. Classified research;
7. Proposed procedures have not been used in humans;
8. Research for which participants would be exposed to additional risks, e.g. breach of confidentiality, phase I studies, previous reports of injury, disproportionate number or severity of adverse events;
9. Previous Administrative Holds or Suspensions of the research due to compliance, record-keeping or other concerns; and/or
10. Recommendations from other Institutional committees (e.g., IACUC or IBC).

Please see the Comprehensive Policies and Procedures for the IRB online www.mtsu.edu/irb or in the Office of Compliance for further reference.

IX. VIOLATION OF POLICY

A. If allegations of violation of policies on research with human subjects are made, the IRB and the Office of Compliance will investigate the allegations.

B. If the IRB determines that violation of the policy have taken place, the IRB will take one or more of the following actions:

1. The project will be halted and researchers informed of corrections to be made before research can begin again. These corrections must be implemented and presented to the Board for review within 30 days of the notification.

2. Violations of the policy will be reported to the appropriate offices, including, but not limited to, the Office of Compliance and Institutional Official.

3. Violations of the policy may be reported to the Office of Human Research Protections if it falls under the following criteria:

    a. Non-exempt research (unless there are repeat violations under exempt review);
    b. conducted or supported by HHS;
    c. conducted or supported by any non-HHS federal department or agency that has adopted the Common Rule and is covered by a Federalwide Assurance (FWA) determined to be appropriate for such research; or
    d. covered by an FWA, regardless of funding source.

4. If the IRB determines that the allegation also violates the Policy on Misconduct in Scholarly Activities and Research, the allegations will be sent to the Institutional Official for inquiry/investigation.

Please see the Comprehensive Policies and Procedures for the IRB online www.mtsu.edu/irb or in the Office of Compliance for further reference. Faculty may also want to reference the Policies and Procedures for Tenure at http://www.mtsu.edu/~provost/tenpro/.

Revisions: September 19, 1995; November 30, 2009; January 19, 2012.