I. INTRODUCTION

Middle Tennessee State University will adhere to the Department of Health and Human Services (DHHS) policy on "Protection of Human Subjects" (Title 45 CFR, Part 46, revised June 18, 1991) and the "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (April 18, 1979) in all research activities requiring human subjects. This includes all projects whether funded internally and/or externally. All research projects involving human subjects will be reviewed and monitored by the Institutional Review Board (IRB) in accordance with the above-mentioned policies.

II. DEFINITIONS

Research means 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.

Human subject means 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 includes 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).

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

Prisoner means 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.

Minimal risk means that 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 and tests.

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.

The informed consent document must provide each subject with the following:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

The following additional information is to be provided to subjects, where appropriate:
1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is/may become pregnant) which are currently unforeseeable;

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

3. Any additional costs to the subject that may result from participation in the research;

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

6. The approximate number of subjects involved in the study.

III. COMMITTEE MEMBERSHIP

The IRB shall consist of at least thirteen (13) members. The IRB membership shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The membership shall include at least:

1. Two members from each of the academic colleges.
   - At least one member must be from the graduate faculty
   - One member whose primary concerns are in scientific areas.
   - One member whose primary concerns are in nonscientific areas.

2. One member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

3. One undergraduate and one graduate student.

The Director of Sponsored Programs shall serve as an ex-officio member of the IRB. The IRB may at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Members shall serve on the IRB for three years.

IV. FUNCTIONS AND RESPONSIBILITIES OF THE INSTITUTIONAL REVIEW BOARD

The IRB shall:

Review and approve, require modifications in (to secure approval), or disapprove proposals for all research activities covered by this policy.

Require information given to subjects as part of informed consent is in accordance with Par. 46.116 of Title 45 CFR Part 46. The IRB may require information, in addition to that specifically mentioned in Par. 46.116, be given to the subjects when in the IRB's
judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

Require documentation of informed consent or may waive documentation accordance with Par. 46.117.

Notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides not to approve a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

V. 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 Vice President for Academic Affairs.

Assume responsibility of execution of IRB policies.

B. Secretary

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

Record the minutes of all IRB meetings.

Assist with the preparation of the agenda.

Forward copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects to the Office of Sponsored Programs.

Maintain records of continuing review activities.

Maintain copies of all correspondence between the IRB and the investigators.

Assist with the preparation of the annual report to the Vice President for Academic Affairs.
VI. 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 OSP Web Page. Special meetings may be called by the Chairperson as deemed necessary for the performance of IRB responsibilities.

2. Protocol applications shall be made available to members for review 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. Absence from fifty percent (50%) of regular meetings without due cause will result in a request by the IRB to the President of the University via the Chairperson for replacement of that member.

VII. REVIEW PROCEDURES

All research activities involving human subjects shall submit the Human Subjects Review Form to the College Representative or to the Office of Sponsored Programs. If the activity is 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 OSP Web Page.

The College Representative shall determine if the research qualifies for an expedited review (See Section VIII). If the research project does qualify, the College Representative will notify the investigator of approval. The College Representative will compile a list of proposals approved through the expedited process and place all materials with the Office of Sponsored Programs. If the research does not qualify for an expedited review, the College Representative may suggest changes or forward the project to the IRB for a full review.

Research proposals must be submitted a minimum of two weeks prior to the scheduled meeting in order to receive full review. The dates of the scheduled meetings will be kept on file in the Office of Sponsored Programs (OSP) and on the OSP Web Page. Applications not received by the deadline date will not be reviewed.

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.

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 two categories: Category I is eligible for "expedited review" and Category II requires "full review". The review procedures for each of these are described below. 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 (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 following categories may be reviewed by the IRB through the expedited review. The categories in this 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 of the school district.

- Research conducted in established or commonly accepted education settings, involving normal education practices, such as (1) research on regular or special education instructional strategies or (2) research on the effectiveness of comparison among instructional techniques, curricula, or classroom management methods.

- Research involving the use of educational tests such as cognitive, diagnostic, personality, aptitude, and achievement tests.

- Anonymous, mail or telephone surveys on innocuous topics or anonymous, non-participating observation of public behavior unless (1) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects, and (2) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- Collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in a manner that subjects cannot be identified.

- Research and demonstration projects which are designed to study, evaluate, or otherwise examine: (1) public benefit or service programs; (2) procedures for obtaining benefits or services under those programs; (3) possible changes in or alternatives to those programs or procedures or (5) possible changes in methods or levels of payment for benefits or services under those programs.

- Taste and food quality evaluation and consumer acceptance studies, (1) if wholesome foods without additives are consumed or (2) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S.D.A.

- Clinical studies of drugs and medical devices only when:
  - Research on drugs for which an investigational new drug application is not required;
• Research on medical devices for which (1) an investigational device exemption application is not required; or (2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared approved labeling.

• Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  • From healthy, nonpregnant adults who weight at least 110 pounds*
  • From other adults and children, considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.*

• Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction.*

• Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Examples: (9a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

• Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

• Collection of data from voice, video, digital, or image recordings made for research purposes.

• Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies.

• Continuing review of research previously approved by the convened IRB as follows:
  • Where (a) the research is permanently closed to the enrollment of new subjects; (b) all subjects have completed all research-related interventions; and (c) the research remains active only for long-term follow-up of subjects; or
  • Where no subjects have been enrolled and no additional risks have been identified; or
• Where the remaining research activities are limited to data analysis.

* Please refer to the NIH web page for further examples (www.nih.gov:80/grants/oprr/numansubjects/expedited98.htm)

**Project Category II (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 above in expedited review), prisoners, and the mentally incompetent
7. Research conducted outside the United States, regardless of the procedures involved

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

**IX. VIOLATION OF POLICY**

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

**B.** If the IRB determines that violation of the policy have taken place, the board 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.

(a) Faculty -- Department Chairs; Dean of Graduate Studies if the research is funded by the Faculty Research and Creative Activities Committee

(b) Graduate Students -- Faculty Advisor; Dean of Graduate Studies; Student Affairs

(c) Undergraduate Students -- Faculty Advisor; Student Affairs
3. 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 Provost for inquiry/investigation.
MIDDLE TENNESSEE STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD

HUMAN SUBJECTS RESEARCH REVIEW FORM

INSTRUCTIONS

- All research involving human subjects must be reviewed and approved prior to initiating the research.
- A completed cover page and all information requested on pages 2-4 must be provided for all projects.
- Based on the specifics of the project, additional information may be required. Please provide this information on separate sheets and detach pages 5-9 before submitting the project.
- The Principal Investigator and, if appropriate, his/her Faculty Supervisor must sign the form on page 4.
- The appropriate number of copies (see below) should be submitted to the address below.

PROJECT CATEGORIES

- The method of review (expedited or full review) depends on the category of research appropriate for the project.
- Although the investigator makes the initial determination of the project's category, it is the IRB which ultimately decides under which category a project will be reviewed.
- If you have any questions regarding the appropriate category for your project, refer to the above policy.

EXPEDITED REVIEW
(SUBMIT ONE COPY ONLY)

- Anonymous, mail or telephone surveys on innocuous topics
- Anonymous, noninteractive nonparticipating observation of public behavior
- Secondary analysis of existing data
- Educational research involving no interaction with students; e.g. observation of intact classes without modifying or disrupting regular classroom activity
- Research involving educational records if information taken from these sources is provided to the researcher in such a manner that subjects cannot be identified
- Research on individual or group behavior of normal adults where there is no psychological intervention, physiological intervention or deception
- Interviews and interactive surveys on non-sensitive topics

FULL REVIEW
(SUBMIT TEN COPIES PLUS ORIGINAL)

- Research which might put subjects at risk
- Research involving psychological or physiological intervention
- Noncurricular, interactive research in schools
- Research involving deception
- Interviews or surveys on sensitive topics
- Research on special populations (e.g., minors, prisoners, and the mentally incompetent)
- Research conducted outside the United States, regardless of the procedure involved

Submit completed forms and address any question to:

Myra Norman
Office of Sponsored Programs
Box 124
Telephone: 5005

PLEASE DETACH THIS SHEET BEFORE SUBMITTING THE REVIEW FORM

NOTE: This form has been adapted from the Human Subjects Research Review Form, The University at Albany, State University of New York
MIDDLE TENNESSEE STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD
HUMAN SUBJECTS RESEARCH REVIEW FORM

☐ Expedited Review  ☐ Full Review

Investigator(s)
name(s)__________________________________________

Project Title________________________________________

________________________________________

Campus telephone ____________________________

Campus address __________________________________

Department or University Unit ________________________

Investigator Status (For each investigator)

☐ Faculty/Staff  ☐ Graduate Student  ☐ Undergraduate Student  ☐ Other

If the principal investigator is a student, list name department and local telephone of faculty supervisor. Please note that THE FACULTY SUPERVISOR MUST INDICATE KNOWLEDGE AND APPROVAL OF THIS PROPOSAL BY SIGNING THIS FORM.

Faculty Supervisor Name ____________________________

Address & Telephone ________________________________

Source of funding for project __________________________

Expected starting date for project ______________________

Is this project expected to continue for more than one year?

☐ Yes  ☐ No  Anticipated Completion Date ________________

Approval for projects is valid for one year only. Investigators must request a continuation of the approval yearly if the activity lasts more than one year. Only two continuations will be granted for a given project. After three years, the project must be resubmitted.
PROJECT DESCRIPTION

- The following information is required for all projects.
- Limit your answers to the space provided. (Further information may be attached to supplement this description, but not to replace it)
- Attach copies of all questionnaires, testing instruments or interview protocols; include any cover letters or instructions to subject.

DESCRIPTION
Provide a BRIEF description, in LAYMAN'S TERMS, of the proposed research:

METHOD (check all that apply)
☐ QUESTIONNAIRE ☐ OBSERVATION ☐ TEST
☐ INTERVIEW ☐ FILES ☐ TASK
☐ TREATMENT
☐ OTHER ____________________________

NUMBER OF SUBJECTS ____________________________

SUBJECT POPULATION (check all that apply)
☐ ADULT ☐ MINOR
☐ PRISONER ☐ MENTALLY RETARDED
☐ MENTALLY ILL ☐ PHYSICALLY ILL
☐ DISABLED ☐ OTHER

Specify: ____________________________
SUBJECT SELECTION
Are subjects to be drawn from the Psychology subject pool? (Y/N) ___
- If yes, a completed sample sign-up sheet must be submitted.
- If no, describe how subjects will be selected for participation in this project and any payment to be received by the subject:

NOTE: If the subjects are to be drawn from an institution or organization (e.g., hospital, social service agency, prison, school, etc.) which has the responsibility for the subjects, then documentation of permission from that institution must be submitted to the Board before final approval can be given.

CONFIDENTIALITY
Specify steps to be taken to guard the anonymity of subjects and/or the confidentiality of their responses. Indicate what personal identifying indicators will be kept on subjects. Specify procedures for storage and ultimate disposal of personal information.

CONSENT
Specify how subjects will be informed of the following: a) the nature of their participation in the project, b) that their participation is voluntary and c) that their responses are confidential. (If a consent form is being used, attach a copy. If presented orally, a copy of presentation must be submitted.)
ADDITIONAL PROCEDURAL INFORMATION
INDICATE BELOW WHETHER YOUR PROJECT INVOLVES ANY OF THE FOLLOWING. FOR EACH ITEM CHECKED, PROVIDE THE REQUESTED INFORMATION IN THE ADDITIONAL PROCEDURAL INFORMATION SECTION BEGINNING ON PAGE 5

☐ A) Risk (p. 5)
☐ B) Minors as subjects (p. 5)
☐ C) Psychological intervention (p. 6)
☐ D) Deception (p. 6)
☐ E) Physiological intervention (p. 7)
☐ F) Biomedical procedures (p. 7)

SIGNATURES

The Principal Investigator must sign this form.

I certify that 1) the information provided for this project is accurate, b) no other procedures will be used in this project, and c) any modifications in this project will be submitted for approval prior to use.

______________________________
Signature of Investigator

______________________________
Date

If the P.I. is a student, his/her Faculty Supervisor must also sign this form.

I certify that this project is under my direct supervision and that I am responsible for insuring that all provisions of approval are complied with by the investigator.

______________________________
Signature of Faculty Supervisor

______________________________
Date

Committee Use Only

NOTE: APPROVAL OF THIS PROJECT BY THE IRB ONLY SIGNIFIES THAT THE PROCEDURES ADEQUATELY PROTECT THE RIGHTS AND WELFARE OF THE SUBJECTS AND SHOULD NOT BE TAKEN TO INDICATE UNIVERSITY APPROVAL TO CONDUCT THE RESEARCH.

Expedited Review

Approved: ________________________________

College Representative

____________
Date

Committee Review

Approved: ________________________________

Committee Chair

____________
Date
C) RESEARCH INVOLVING PSYCHOLOGICAL INTERVENTION

If the subject(s) of the proposed research will be exposed to any psychological intervention such as contrived social situations, manipulation of the subject's attitudes, opinions or self-esteem, psychotherapeutic procedures, or other psychological influences, please provide the information requested in the following items:

1. Identify and describe in detail the PSYCHOLOGICAL INTERVENTION.

2. Identify and describe in detail the BEHAVIOR expected of subject(s) and the context of the behavior during the psychological intervention.

3. Describe how DATA resulting from this procedure will be gathered and recorded.

4. Identify anticipated and possible psychological, physiological, or social CONSEQUENCES of this procedure for the subject(s).

5. Indicate the investigator's competence and identify his/her QUALIFICATIONS, by training and experience, to conduct this procedure. Given name, title, department, address, and telephone number of the individual(s) who will supervise this procedure.

D) DECEPTION

A study is deceptive if false information is given to subjects, false impressions created, or information relating to the subjects' participation is withheld from subjects.

1. Describe in detail the DECEPTION involved, including any instructions to subjects or false impressions created.

2. JUSTIFICATION. Explain in detail why deception is necessary to accomplish the goals of the research. Care should be taken to distinguish cases in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the investigator.

3. Describe, in detail, the plan for DEBRIEFING subjects. Attach a copy of any debriefing statement.
E) RESEARCH INVOLVING PHYSIOLOGICAL INTERVENTION

If the subject(s) of the proposed research will be exposed to any physiological treatments or intervention upon the body by mechanical, electronic, chemical, biological or any other means, please provide the information requested in the following items:

1. Identify and describe in detail the PHYSIOLOGICAL INTERVENTION.

2. Identify and describe in detail the MEANS used to administer the intervention.

3. Identify and describe in detail the BEHAVIOR expected of subject(s) and the behavior of the investigator during the administration of the physiological intervention.

4. Describe how DATA resulting from this procedure will be gathered and recorded.

5. Identify anticipated and possible physiological, psychological, or social CONSEQUENCES of his procedure for the subject(s).

6. Indicate in detail specific steps that will be taken to assure the proper OPERATION AND MAINTENANCE of the means used to administer the intervention. Give particular attention to prevention of accidental harm or injury to the human subject(s).

7. Indicate the investigator's competence and identify his/her QUALIFICATIONS, by training and experience, to conduct this procedure. Give name, title department, address, and telephone number of the individual(s) who will supervise this procedure.

F) BIOMEDICAL PROCEDURES

If the proposed research involves biomedical procedures (e.g., the taking or withholding of medication, ingestion of any food or other substances, injections, blood drawing, or any other procedure which would normally be done under medical supervision), please provide the information requested in the following items.

1. Describe in detail the biomedical PROCEDURES involved in this project.

2. Identify anticipated and possible physiological CONSEQUENCES of this procedures of the subject(s).

3. Identify the SITE where the procedure is to be carried out.

4. Indicate the investigator's competence and identify his/her QUALIFICATIONS, by training and experience, to conduct this procedure. Give name, title, department, and telephone number of the individual(s) who will supervise this procedure.