THE COMMITTEE FOR THE PROTECTION OF RIGHTS AND WELFARE OF HUMAN SUBJECTS INVOLVED IN RESEARCH

GENERAL INFORMATION

BACKGROUND

The Department of Health and Human Services (DHHS) has issued guidelines to institutions doing research involving the use of human subjects and/or data collected from human subjects. Among other matters, these guidelines (45 CFR 46) are concerned with the protection of confidentiality of data and protection against physical, psychological, social and legal risks. It is the policy of Tennessee State University that all research involving human subjects, whether federally funded or not, must be reviewed for adherence to the guidelines. Research projects may not be initiated until and unless the project is approved under these guidelines.

All individuals conducting or supervising human subject research (e.g., PIs, department heads, research administrators) should obtain copies of and review three documents available on the Research and Sponsored Programs website - 1) Assurance of Compliance with HHS Regulations for Protection of Research Subjects, Tennessee State University; 2) Code of Federal Regulations (45 CFR 46), Protection of Human Subjects; 3) Ethical Principles and Guidelines for Protection of Human Subjects of Research (the "Belmont Report"). In addition, all individuals conducting research using human subjects must complete the mandatory training program referenced on the website (Mandatory Training for Researchers using Human Subjects). Supervisors of dissertations, theses, and student projects should apprise students of the TSU human subjects in research policies and procedures, and ensure that they also complete the mandatory training for human subjects in research as referenced above.

OUTLINE OF PROCEDURES

The following is summary of procedures to be followed for all proposals for research projects (Senior Projects, Theses, Dissertations, funded and non-funded faculty research) involving human subjects.

1. Research investigators (including faculty and students) shall prepare a complete description of the proposed research, including provision for the adequate protection of rights and welfare of prospective research subjects. Samples of the proposed Informed Consent Form must be included. Use the attached "Research Proposal Form". Additional copies are available in the Office of Research and Sponsored Programs, Research and Sponsored Programs Building, suite 1A.

2. Department Heads through appropriate procedures established within their respective departments are responsible for reviewing research protocols for ethical considerations and scientific merit. A preliminary determination shall be made as to whether the research is in the "Exempt" category. The categories of research that may be exempt form review by the Committee for the Protection of Rights and Welfare of Human Subjects Involved in Research include:
   a) Research involving normal educational practices
   b) Research involving standard educational tests or assessment instruments
   c) Survey research
   d) Observational Research

Revised September 2008
e) Research involving existing data

f) Research involving programs of the Department of Health and Human Services.

3. All approved protocols shall be submitted by the Department Head to the Office of Research and Sponsored Programs, which will make a final determination whether a protocol qualifies for exemption. All nonexempt research protocols will be forwarded to the Institutional Review Board (The committee for the Protection of Rights and Welfare of Human Subjects Involved in Research).

4. The Committee shall review all nonexempt protocols, and have the authority to approve, require modification in or disapprove all research activities. The Committee shall approve research if:

a. The risks to subjects are minimized;

b. Risks to subjects are reasonable in relation to anticipated benefits to subjects and the importance of knowledge expected in result;

c. Selection of subjects is equitable;

d. Informed consent will be sought from each prospective subject, when appropriate;

e. There are adequate provisions to protect the confidentiality of data;

5. Basic Elements of Informed Consent as requested on the Research Proposal Form (to be written in language understandable to the subject or representative):

a. A statement that the study involved 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;

b. A description of any reasonable foreseeable risks or discomforts to the subjects;

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

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

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

f. 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;
g. 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 subjects' and

h. A statement that participation in voluntary, refusal to participate will involve no penalty or loss of benefits to which the subjects 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.

**SUBMISSION**

Three (3) copies of the Human Subjects Research Proposal form, Instruments, Consent forms, Letters of Cooperation (if application), and Certificate of Completion of Mandatory Training may be submitted to the Division of Research and Sponsored Programs, RSP Building, Suite 1A. (The Human Subjects Research Proposal form may be completed and submitted electronically to irb@tnstate.edu)

**DEADLINES**

Meetings of the Committee shall occur on a monthly basis or will be called when the Chairperson judges necessary. Completed Research Proposal Forms must be submitted to the Office of Research and Sponsored Programs not later than the tenth day of each month for consideration during a given month. It is the intent of the committee to provide feedback on proposals within 20 working days of the submission dates of the 1st through the 10th of each month. Proposals submitted after the 10th, will be considered the following month.