TENNESSEE STATE UNIVERSITY

HUMAN SUBJECTS COMMITTEE

RESEARCH PROPOSAL FORM

This proposal is: (check where applicable)

Dissertation Research: _____ ***Grant Proposal:*** _____ ***Funding Agency:*** _____

Master's Thesis Research: _____ ***Faculty Research:*** _____

Undergraduate Research: _____ ***Other:*** _____

IDENTIFICATION INFORMATION: (Complete all items. Use "N/A" if necessary).

1. Title of Proposal: _____

_____

2. Date: _____

3. Principal Researcher: _____ ***E-mail Address:***_____

Department: _____

4. Campus Address: _____

_____

_____

5. Telephone Number: _____

6. Other Researchers: _____

7. Faculty Advisor (if applicable): _____ ***E-mail- Address:***_____

8. Former Title of Proposal (if applicable): _____

9. Identify any other previous committee reviews, dates and results: _____

_____

10. This proposal is: ____ ***New*** ____***An Amendment***
Yearly Progress Report for Previously Approved Project (only include proposed changes. Sub-Study Under an Umbrella (e.g. Research Center, Training, Grant, etc…)

THE COMMITTEE FOR THE PROTECTION OF RIGHTS AND WELFARE HAVE 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 thee 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, Agricultural Research and Extension, room 114.

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

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 Sponsored Research, 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.

DEADLINES

Convened meetings of the Committee shall occur once per month or on a called basis when the Chairperson judges a meeting to be necessary. To be considered at a given meeting, completed Research Proposal Forms must be submitted to the Office of Research and Sponsored Programs not later than ten days prior to the scheduled meetings. The schedule for submissions and meetings is posted on the Research and Sponsored Programs web site at www.tnstate.edu/research. Look on the menu under "Compliance".

TENNESSEE STATE UNIVERSITY

RESEARCH PROPOSAL NON-EXEMPT FORM

BRIEF DESCRIPTION OF PROGRAM

If this proposal has been approved by this committee previously and is being resubmitted with any modifications, the modifications. (Include former title and review data in identification information on Title Page of form).

I. Research Plan

A. Scientific rationales:

B. Specific objectives:

II. Describe types, numbers, age and sources of subjects to be studies. (From where will the subjects be recruited? How will subjects be recruited)?

III. Identify all procedures that will be carried out with each type of subject in chronological order. Attach copies of tests or instruments to be used, and consent forms.

IV. Dose the project offers a direct benefit to each type of subject? (it need not)
_____ yes _____no. If yes describe.

V. Describe anticipated risks, discomforts, or inconveniences that might be associated with the procedures (that are beyond what subjects typically encounter in everyday life).

VI. What precautions will be taken in those procedures where potential risk may be involved?

VII. What steps will be taken for maintaining the subjects' confidentiality, rights, privacy, and well being? Include plans for maintaining confidentiality of documents and data, and access to such.

VIII. Is any element of deception of the subjects necessary for this research"

_____ yes _____ no. If answer is "Yes" describe the nature of the deception and the procedure to counteract (undo) the deception.

IX. Procedure for obtaining the participants' informed consent:

A. Written consent form will be used _____
B. An oral presentation will be made _____
C. Other _____

Regardless of the method chosen, the researcher must attach to this proposal the completed consent form or a description of the alternate procedure. If no consent is considered necessary, please explain.

X. If other institutions are involved in any way in this research sponsored by Tennessee State University, submit letters of cooperation form the administrative authority in these institutions.

XI. The researcher agrees to seek prior approval form the committee for any changes in title, experimental procedures, informed consent procedures or working of informed consent letter, or other aspects of this proposal. The research further agrees to notify the committee immediately of any adverse effects experienced by subjects participating in this study.

SIGNATURES:

_____
Principal Researcher Date

_____
Faculty Advisor (if applicable) Date

_____
Department Chairperson Date

_____
IRB Chair or Reviewer Date

NOTE: Return completed Proposal Form and all attachments to:

The Office of Research and Sponsored Programs

Pick up approved forms from: Office of Research and Sponsored Programs, Agricultural Research and Extension, Room 114 Tennessee State University, Box 9519, 3500 John A. Merritt Boulevard, Nashville, Tennessee 37209-1561

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Director of Research and Sponsored Programs Date