Research at TSU
Institutional Review Board

For the Protection of Human Subjects

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What is the Institutional Review Board (IRB)?

- A board or committee organized at the University to provide review at the institutional level for ethical concerns in research, such as laboratory animal care and the use of human subjects in research.

Protecting Human Research Participants (NIH Training)

- All persons seeking IRB approval for research at Tennessee State University are required to complete the training course listed below:

- http://phrp.nihtraining.com

- This free, three-hour, web-based tutorial presents information about the rights and welfare of human participants in research.

Protecting Human Research Participants (NIH Training)

- This course satisfies the NIH human subjects training requirement for obtaining Federal Funds.

  - The certificate of completion must be printed out and attached to all IRB protocols which are submitted before approval is granted.

Protecting Human Research Participants (NIH Training)

- Step # 1
  - Go to http://phrp.nihtraining.com
- Step # 2
  - If you are entering the course for the first time, you must complete a registration form to register a new account. Click "Registration."

Protecting Human Research Participants (NIH Training)

- Step # 3
  - Complete the enrollment form and then click “Create Account” at the bottom of the form.

- Step # 4
  - Follow the on screen directions which explain how to complete the course and print out the certificate of completion.

Understanding The IRB Process

- The following is a summary of procedures to be followed for all proposals for research projects involving human subjects. This includes Senior Projects, Theses, Dissertations, Funded and Non-Funded Faculty Research.

Understanding The IRB Process

- The TSU IRB conducts two (2) types of reviews:
  - Expedited Review
  - Full Review

- Exempt research protocols receive an expedited review.

Understanding The IRB Process

- You and your advisor 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" or “Non-Exempt” category.

Submit by Email

Print Form

Tennessee State University Institutional Review Board

Research Exempt from IRB Committee Review

Category: Use of Existing Data: Records Review and Analysis

1. Project Title:

2. Principal Investigator
   a. Name:
   b. E-mail :
   c. Telephone:

   d. □ Faculty □ Student □ Other
   e. Human Subjects Training Completed? □ Yes □ Pending

3. Brief description of your research methodology and source of data.

4. Is the data you are gathering publicly available? □ Yes □ No
   a. If, No do you have permission to access the records? □ Yes □ No
   b. Will the records you received be void of **ALL** identifiers that would make it possible to identify subject?
      □ Yes
      □ **No: This research does not qualify for exempt status.**
      Please complete the full IRB application.

5. I assure the IRB that the information provided in this form is accurate. I will seek and obtain prior approval from the IRB for any substantive changes or modifications to this research proposal. I will report any unanticipated problems with the procedures outlined in this study.

_____ _____

Signature: Principle Investigator Date

_____ _____

Signature: Advisor (if applicable) Date

IRB # HS 20_____ -_____ Approved :_____ Not Approved:_____

IBR Chair (or designate) _____ _____

Revised: 01/2009 Signature Date

Understanding The IRB Process

- All approved protocols shall be submitted to the Office of Research and Sponsored Programs, which, in consultation with the IRB Chair, will make a final determination whether a protocol qualifies for exemption.
  - Exemption: Archival Data or Existing Database

- All non-exempt research protocols will be forwarded to the full Institutional Review Board Committee for review.

Understanding The IRB Process

- The Committee reviews all protocols, and have the authority to approve, require modification, or disapprove all research activities. The Committee shall approve research if:
  1. the risks to subjects are minimized
  2. risks to subjects are reasonable in relation to anticipated benefits to subjects and the importance of knowledge expected in results
  3. selection of subjects is equitable
  4. informed consent will be sought from each prospective subject, when appropriate
  5. there are adequate provisions to protect the confidentiality of data

IRB Submission Step 1

- Complete the IRB Application:
  - Find out which type of review (Expedited/Exempt or Full Review) the research study will qualify under.
  - Complete the appropriate IRB application. Respond to all of the items (include “not applicable” where appropriate).
  - Include all necessary materials including consent forms, instruments, assessment measures or questionnaires, debriefing forms, letters of cooperation, flyers, etc.

IBR Submission Step 2

- Deliver one (1) copy of the TSU application and one (1) copy of the NIH certificate – with any requisite supporting documents to the Division of Research and Sponsored Programs (RSP), RSP Building, Suite 1A.

IBR Submission Step 3

- Upon preliminary processing of these materials by RSP, the researcher will receive a confirmation email which includes the IRB routing number (HS2009-xxxx) assigned to the proposal.

Preparing the IRB forms

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...)

Revised 25 Sep 2007

TENNESSEE STATE UNIVERSITY

RESEARCH PROPOSAL NON-EXEMPT FORM

BRIEF DESCRIPTION OF PROGRAM

I. Research Plan

A. Scientific rationales:

B. Specific objectives:

II. Describe types, numbers, age and sources of subjects to be studied. (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. Does the project offer 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

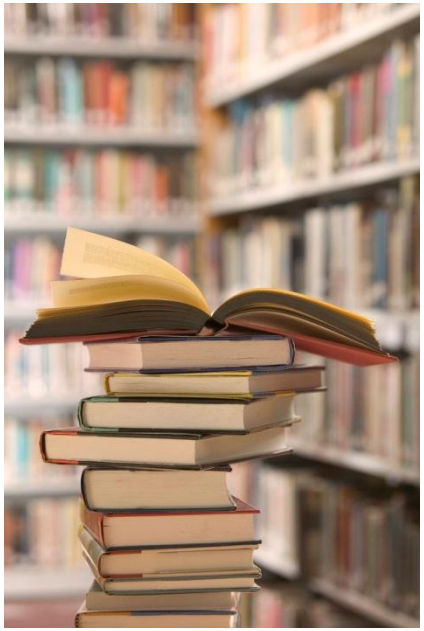
Pick up approved forms from: Office of Research and Sponsored Programs, Research and Sponsored Programs Building, Suite 1A, Tennessee State University, Box 9519, 3500 John A. Merritt Boulevard, Nashville, Tennessee 37209-1561

_____
VP for Research and Sponsored Programs Date

I. Research Plan

A. Scientific Rationale

B. Specific objectives



Scientific Rationale

- Concerned with the relationship among variables.
  - Measurable quantities that vary or change under different circumstances.
  - Variables are measurable quantities.

Scientific Rationale

- Why ?
- Whom ?
- How ?
- When ?

- Why
  - Establishes the need for the study
  - Hypothesis – a statement of what they expect the results to show
- Whom
  - Decide whether to observe an entire population or just a sample of the population
  - Must consider how to obtain an unbiased sample

- How
  - Selection of the instrument(s) (for collection of data).
- When
  - Decide when using the instrument to obtain the most valid results.

Participants/Subjects

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

Recruiting Participants

- If you plan to –
  - Use flyers: include a copy of the flyer
  - Get participants from a class: include written permission from instructor.
  - Use data from an external agency: include letter of cooperation.
  - Get participants from a church: give the name of the church and state exactly how it will occur.
    - (Will flyers be passed out at the church? Will the pastor make an announcement during the service?)

EXAMPLE

- The following examples **do not** give enough information to clearly show how participants will be recruited:
  - I will get volunteers from my school or church.
  - I will get volunteers from the Nashville area.
  - I will get students from Tennessee State University.

PROCEDURE

- III. Identify all procedures that will be carried out with each type of subject in chronological order.
  - Survey, Tests or Instruments
  - Consent Forms

  - There must be enough detail so that anyone wanting to replicate your study would be able to recruit participants in the same manner you did.

BENEFIT vs. RISK

- IV. Does the project offer a direct benefit to each type of subject?
- V. Any risks, discomforts, or inconveniences associated with the procedures?
- VI. What precautions will be taken in those procedures where potential risk may be involved?

CONFIDENTIALITY

- VII. What steps will be taken for maintaining the subjects' confidentiality, rights, privacy, and well being?

- Include plans for maintaining confidentiality of document and access to such.

INFORMED CONSENT

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

- IX. Procedure for obtaining the participants' informed consent:
  - Written consent
  - An oral presentation
  - Other

Basic Elements of Informed Consent

- Should be written in language understandable to the subject or representative.
- 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.
  - Identification of any procedures which are experimental.

Basic Elements of Informed Consent

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

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

Basic Elements of Informed Consent

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

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

Basic Elements of Informed Consent

- For research involving more than minimal risk:
  - An explanation as to whether any compensation.
  - An explanation as to whether any medical treatments are available if injury occurs (describe the treatments).
  - Where further information about treatment may be obtained.
  - Whom to contact for answers to pertinent questions about the research and research subjects' rights.
  - Whom to contact in the event of a research-related injury to the subjects.

Basic Elements of Informed Consent

- A statement that:
  - Participation is voluntary.
  - Refusal to participate will involve no penalty or loss of benefits to which the subjects is otherwise entitled.
  - The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Letters of Support

- X. If other entities are involved in any way, you must submit letters of cooperation and/or support from the administrative authority in these institutions.

IRB DEADLINES

- 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.

IRB DEADLINES

- 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.

Questions?

For more information
Email irb@tnstate.edu