

FORM B GUIDELINES AND APPLICATION INSTRUCTIONS

Researchers: Please discuss your proposed research project with your Departmental Review Committee or with Research Compliance Services of the Office of Research, (865) 974-3466, before you begin preparing a Form B application. If your project only exposes your subjects to minimal risks and you do not intend to use subjects from vulnerable populations, then it may be possible to use a Form A application. Remember that all research using human subjects must be approved before the subjects are contacted and research begins. With this approval you are assured that the research is in compliance with sanctioned university research policies and procedures.

Form B Header The header on the first page of every Form B should be prepared as follows:

[Note: Please Number the Pages of the Form B Application]

FORM B

IRB # _____

Date Received in Office of Research _____

THE UNIVERSITY OF TENNESSEE

Application for Review of Research Involving Human Subjects

Body of Form B -- The body of the Form B should include the following information:

(Please note that headings and subheadings printed in bold type must be included in your Form B application even if your response under that heading or subheading is N/A.)

I. IDENTIFICATION OF PROJECT

1. **Principal Investigator (PI) or Co-Principal Investigators (Co-PI):**
 - The person or persons responsible for the design and implementation of the research project are considered the PI or Co-PIs and should be listed in this section.
 - For each PI or Co-PI, include the name of the college and the name of the department, the mailing address (home or campus), telephone number, and e-mail address. All communications and correspondence will be directed to the first person listed as principal or co-principal investigator, unless otherwise requested and noted on this form.

Faculty Advisors: For projects that will form the basis of students' theses and dissertations, students should be listed as investigators and their faculty advisors should be identified in this section. The names of the advisor's college and department or unit, campus address, campus telephone number, and e-mail address should be included. (Please note that faculty advisors are not automatically considered project investigators unless they are listed as a PI or Co-PI Section I.)

Department: State the name of the department located in the college.

2. **Project Classification:** Provide an appropriate description (e.g., Research Project, Dissertation, Thesis, etc.)
3. **Project Title:** Provide the title of your project. If a title has not been determined, please provide a tentative title for the project. If external support is sought or has been obtained, use the title of the project listed on the application for external support in creating a title for this project.
4. **Starting Date:** Specify an intended starting date or state "Upon IRB Approval".
5. **Estimated Completion Date:**
6. **External Funding:** (If this project is not externally funded, enter "N/A" and go on to Section II.): If external funding is sought or was obtained for this project, please provide the following information:
 - a. **Grant/Contract Submission Deadline:**
 - b. **Funding Agency:**
 - c. **Sponsor ID Number** (if known):
 - d. **UT Proposal Number** (if known):

II. PROJECT OBJECTIVES:

Provide a brief rationale of the project in non-technical language so that reviewers from other disciplines can understand and identify the objectives and goals of the research project. The statement of objectives must be clear and accurate, revealing to reviewers the anticipated significance of the proposed research. If you are seeking external support for this project, the objectives listed in this section must coincide with the objectives and goals made in any application for support. In addition, the objectives listed in this section should coincide fully with the objectives described to participants in the consent form. (If investigators have reason to withhold information about the objectives from participants, they must justify this action in Section VII.)

III. DESCRIPTION AND SOURCE OF RESEARCH PARTICIPANTS

1. Describe your participants.
2. How you will gain access to those participants?
3. Include the criteria for selection and exclusion.
4. Include the number of participants you anticipate using.

Explain the rationale for using any special groups, such as children, pregnant women, prisoners, students, cognitively impaired, institutionalized individuals, or any participants whose ability to give voluntary and informed consent may be questioned. Give a rationale for projects that restrict participants based on gender.

Identify the source of your participants (school systems, hospitals, colleges and universities, private companies, religious groups, governmental entities, community groups, etc.) and describe the methods for recruiting participants. Letters of permission are required from entities other than UT. Letters of permission should authorize the investigators to contact potential participants, to use of the facilities, or records of that entity. These letters must accompany the Form B application at the time of submission for review.

Disclose any relationship between researchers and participants - such as, teacher/student; employer/employee; or superintendent/principal/teacher.

If an incentive is to be used, identify the incentive for participation, payment procedures, and provide a rationale for using the incentive. Keep in mind that the value of incentives to participants is relative, and reviewers may consider highly valued incentives coercive.

Investigators who plan to recruit UT students and offer extra course credit for student participation must follow the procedures maintained in the department whose classes are used. Departmental letters of permission must be attached to the Form B application.

IV. METHODS AND PROCEDURES

Clearly and concisely describe in non-technical language the data collection and experimental research methods used in this project that will directly involve human participants. This section should be consistent in every detail with the description provided to participants in the consent form or procedure. (Any omission or deviation in the methods and procedures information provided in the consent process must be justified in Section VII.) Include non-technical descriptions of stresses to participants, experimental manipulations, tests or measures, surveys, interviews, observations, photography, and video and audio recordings. Clearly distinguish between control and comparison, and experimental and treatment participant groups.

If the project involves audio taping, videotaping or photography of participants, explain the need for these methods and describe how the data will be used. Describe how the film or tapes will be stored, and when and how they will be destroyed. Identify the individuals who will have access to the tapes or film, and on what basis they will have access. If the tapes or film are to be used in the future, explain the procedures for obtaining participants' informed consent for those uses, and the conditions under which the tapes or film would be used.

Describe how you will analyze and interpret the data.

V. SPECIFIC RISKS AND PROTECTION MEASURES

Specify all potential risks to participants of the proposed research. Estimate the nature and amount of potential risk, stress, or discomfort, and assess the likelihood and its seriousness. Describe the precautions you will take to reduce risk and assess the effectiveness of these protective measures. Identify specific controls, screening methods, and follow-up to assure no residual physical, psychological, or social damage to the participants. If appropriate, include a description of the means you will use to assist or treat participants who may incur injury from one or more of the risks identified in this section. Provide sufficient detail to permit reviewers, who may not be familiar with your area of study to evaluate any specific risks to the participants of this research.

Include the methods and provisions by which you will address the issue of anonymity or confidentiality of data. Note that anonymity is only possible if the investigator cannot discover the participant's identity from data collected. In either case, describe how you will maintain the confidentiality of the participants' data. Identify security measures, such as limiting access to data, purging identification information from data, securing files, and other appropriate measures. Identify to whom access is given.

If the confidentiality of the participants' identities or data cannot or will not be protected, please state how you will inform participants of this fact before their participation.

VI. BENEFITS

Evaluate the reasonableness of the risks stated in Section V in relation to the anticipated benefits (e.g., desired outcomes), if any, to the participants and/or to society. If the risks are minimal, please state that the risks are minimal and include a statement of anticipated benefits.

Note that in most research projects, the only relevant benefits are those that contribute to generalizable knowledge in a field of research. In these cases, participant benefits are incidental. Please do not inflate the significance of incidental benefits to participants in your Form B application or your informed consent procedures.

Please note that payment for participation in research is an incentive for participation, and should not be considered a "benefit" of the research.

VII. METHODS FOR OBTAINING "INFORMED CONSENT" FROM PARTICIPANTS

Please state the methods you will use to obtain legally effective informed consent, assent, or permission (as applicable) from participants or participants' legally authorized representatives. Clearly describe how you will seek consent from participants in a manner that allows them sufficient opportunity to consider whether to participate, and that minimizes the possibility of coercion or undue influence. Indicate that the language used in your informed consent procedure is understandable to your participants or their legally authorized representatives. As you describe your informed consent procedures keep in mind that the following procedures are typically used to obtain legally effective informed consent:

1. Use of a written consent document with all the basic elements of informed consent. This form is signed by the participant or a legally authorized representative and an extra copy provided for participant's use and information. A sample consent form is available on the Office of Research's Forms web page.

2. Use of a "short form" written consent document indicating that the basic elements of informed consent have been presented orally to each participant or their legally authorized representatives. Written summaries of what is to be said to the participant should be attached to the Form B for approval by the IRB. The "short form" is to be signed by the participant or a legally authorized representative, and by a witness to the oral presentation and participant's signature. An extra copy should be provided for the participant's use and information.
3. Information sheet - written consent document indicating the basic elements of informed consent. The information sheet is not signed. A sample study information sheet form is available on the Office of Research's Forms web page.

(See attached examples for the above)

The IRB will approve other procedures, if you explain your need for an alternative consent process. Provision of informed consent by alternative means must be approved by the IRB in the minutes and signed by the IRB Chair. Criteria for approval include (but are not limited to) the following:

1. The research involves no more than minimal risk to the participants;
2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Complete Section VII by stating the method and place of storage for signed consent documents. During your research project storing signed informed consent forms at locations other than UT may be necessary; however, the IRB must approve these sites. For legal purposes, signed consent documents must be kept on the UT campus for three years following completion of the research and be accessible to authorized UT personnel.

As you prepare your consent form or procedure, please include the following basic elements of informed consent:

1. Provide a statement indicating that the study involves human research. Describe the purposes of the research and state the expected duration of the participant's involvement in the research project. Describe the procedures to be followed that will directly involve human participants, and specifically identify any procedures that are experimental.
2. Identify and describe any reasonably foreseeable risks to the participant or potential discomforts the participant may experience during the term of this research. If none, please explain why no participant risks or discomforts are anticipated.
3. Describe any benefits to the participant (or to others) that may reasonably be expected from this research.
4. Provide a statement disclosing appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
5. Provide a statement describing the procedure for maintaining the participant's files/records. Will the records identifying the participant remain confidential? Where will they be stored? Who will have access to them?
6. For research involving more than minimal risk to the participant, state whether any financial compensation or any medical treatments are available should an injury occur. If so, describe the nature and extent of the available compensation and medical treatments. Indicate where further information on this subject may be obtained.
7. Identify the individual who may be contacted for responses to pertinent questions about the research and the rights of the research participant.
8. Include a statement specifically noting the following: (a) participation in the research is voluntary, (b) refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and (c) the participant may withdraw from the research project at any time without penalty of loss of benefits to which he or she is otherwise entitled.

Additional elements of informed consent may be required in some cases. Please check with your Departmental Review Committee or the Office of Research Compliance Services for further information.

VIII. QUALIFICATIONS OF THE INVESTIGATOR(S)

Investigators must specify their relevant qualifications and those of other investigators involved in this project to perform the proposed research. Include qualifications of personnel working on portions of the research where special training, certification, or licensing is required for the performance of their tasks. Experience and expertise is required when involving participants classified as vulnerable, such as children, pregnant women, prisoners, cognitively impaired or institutionalized individuals.

IX. FACILITIES AND EQUIPMENT TO BE USED IN THE RESEARCH

Please provide a brief description of the facilities that will be used during the project research, with an evaluation of their adequacy for the intended project. Include a brief description of the equipment to be used for storage and analysis of data.

If a project is to be conducted in a non-UT facility, an original letter of permission to use the non-UT facility must accompany the Form B. Letters of permission must be on the letterhead of the organization and signed by authorized officials. If public school or school system facilities are to be used, letters of permission from authorized officials in the superintendent of schools office, and possibly from school principals must accompany the Form B.

X. RESPONSIBILITY OF THE PRINCIPAL/CO-PRINCIPAL INVESTIGATOR(S)

You must enter the following information verbatim in Section X:

By compliance with the policies established by the Institutional Review Board of The University of Tennessee, the principal investigator(s) subscribe to the principles stated in "The Belmont Report" and standards of professional ethics in all research, development, and related activities involving human participants under the auspices of The University of Tennessee. The principal investigator(s) further agree that:

1. Approval will be obtained from the Institutional Review Board prior to instituting any change in this research project.
2. Development of any unexpected risks will be immediately reported to the Research Compliance Services section.
3. An annual review and progress report (Form R) will be completed and submitted when requested by the Institutional Review Board.

- Signed informed consent documents will be kept for the duration of the project and for at least three years thereafter at a location approved by the Institutional Review Board.

XI. SIGNATURES

When you submit your Form B applications for review note that all signatures must be original. As your Form B application moves through the review process, you should maintain two identical Form B applications both of which contain original signatures. As PI or Co-PI, you should keep one copy of the Form B with original signatures and submit the other Form B with original signatures for review.

Use the following format to prepare your signature section (as needed, add signature lines for all Co-Principal Investigators, collaborating and student investigators, faculty advisors, and additional department heads and DRC chairs).

Principal Investigator _____

Signature _____ **Date** _____

Co-Principal Investigator _____

Signature _____ **Date** _____

Student Advisor (if any) _____

Signature _____ **Date** _____

XII. DEPARTMENT REVIEW AND APPROVAL

The IRB departmental review committee has reviewed and approved the application described above. The DRC recommends that this application be reviewed as:

Expedited Review -- Category(s): _____

OR

Full IRB Review

Chair, DRC _____

Signature _____ Date _____

Department Head _____

Signature _____ Date _____

Protocol sent to Research Compliance Services for final approval on
(Date) _____

Approved:
Research Compliance Services
Office of Research
1534 White Avenue

Signature _____ Date _____