

**Guidelines for preparing a Proposal for IRB Review
TTU Institutional Review Board Committee**

First, fill in the information requested on **Form A**

Then, complete this document that addresses each of the items identified. **TYPE ALL REQUIRED INFORMATION**

1. Statement of Purpose and Background

In one or two paragraphs, state the purpose of the research and relevant background information to provide a rationale for the proposed research. Provide a justification for the use of humans in the research if the project could conceivably use some other source of data.

2. Research Design and Methods

Discuss the data collection methods, the research activities and any devices, tests, questionnaires, interview guides, or other instruments that will be used. If applicable, include information such as the number of groups, types of groups, number participants in each group, and other relevant information. Attach copies of interview questions and a copy of any survey instruments that will be administered. If applicable, identify any medical devices or equipment that will be used in the study. Study Location: Identify the location and setting where subjects will participate in this research and address any special considerations.

3. Subjects

3.a) Characteristics of the subjects: How many, their gender, age range, ethnicity, etc. Use the list on Form A, page 2 to remind you of the main categories. If you will use special or vulnerable populations where ability to provide informed consent may be limited, provide a rationale for including them. Examples of special populations include children, pregnant women, prisoners, cognitively impaired individuals, frail elderly persons, etc.

3.b) If recruiting human subjects, provide a listing of the selection criteria that will be used, discuss the methods of recruitment, and provide details on the recruitment source. Selection Criteria: How will you determine who is included or excluded? Who makes the decision? Recruitment Methods: Describe how you will identify and recruit subjects. Submit a copy of the flyer or advertisement if you will be advertising for subjects. (If subjects will be identified through private records, the holder of the records must make the initial contact with the subject.) Include a statement about how the recruitment will ensure voluntary participation and not single out or embarrass individuals who choose not to participate. Recruitment source: Identify the institutions from which you will recruit subjects. If appropriate, include a letter from that institution/organization indicating support of the study.

4. Informed Consent Process:

Describe who will make the initial contact with potential subjects and how the research will be explained to them. Include information about how the informed consent agreement will be introduced and note any other measures to be used to assess the potential subject's understanding of what will be asked of him/her. Be sure to build in adequate time for prospective subjects to reflect on whether or not they want to participate. **ATTACH a copy of the informed consent form. DO NOT PASTE THE INFORMED CONSENT FORM BELOW.**

5. Project Management and Risks

5.a.1) Risks and Potential Problems: Identify potential or known physical, psychological, social, and economic or legal risks that might be associated with participation in the research. These might be direct risks or the result of a subject's name accidentally being linked to his/her responses. Discuss whether the risks are minimal (no greater than normal daily risks) or significant. **Assessment of Risk:** Assess whether the risks and inconveniences associated with a subject's participation in the research are reasonable in relation to the anticipated benefits to the subjects or in relation to the knowledge that may reasonably be expected to result from the research.

5.a.2) Management of Risks: Describe precautions, safeguards, or other steps incorporated into the research activity to reduce or limit the severity or likelihood of harm. These might include extra precautions in storing data or coding personal identifiers.

5.b) Deception or Incomplete Disclosure: If applicable, fully describe and justify the use of deception in this research. Include a description of the debriefing practices that are proposed.

5.c) Confidentiality: Describe provisions made to maintain confidentiality of data. Who will have access to the collected data, where will it be stored, and for how long?

6. Potential Benefits

Describe the anticipated benefits to (a) the subject, (b) the population from which the subject is drawn, and (c) society/science expected to result from this research. (Do **not** include compensation or incentives that might be offered to subjects.)

7. Costs, Compensation and Incentives

Describe any costs that the subject may incur as a result of participation (charges for tests, travel, lost work time, etc.). If compensation or an incentive is offered for participation, provide details of this payment. Indicate whether the subject is compensated for the number of procedures, the time involved, or some other basis for payment. Indicate whether payment is made by check, cash, or money order, and whether the amount is prorated if the subject decides to discontinue participation. Indicate how the value of the incentive was determined. Compensation/incentives should be appropriate but not excessive to a degree that would unduly influence a potential subject's decision to participate.

The responses to these items should be submitted along with a cover sheet (Form A and Form C) and other required information (e.g., copies of informed consent forms) to the Office of Research, TTU Box 5036

- **Expedited Review: 1 Copy of Forms A-C and other required information (e.g., copies of informed consent forms) MUST be sent**
- **Full Board Review: 14 Copies of Forms A-C and other required information (e.g., copies of informed consent forms) MUST be sent**

Remember: Subject recruitment and data collection may not be initiated prior to formal written approval (return of stamped copy) from Committee for the Protection of Human Subjects

This Section to be Completed by the Office of Research

Expedited Review Status

Category(s) for Expedited Review (if applicable): _____

This Research Has Been Approved by an Expedited Review: Yes _____ No _____

Approved By: _____

Name / Signature / Date

Approved By: _____

Name / Signature / Date

Approved By: _____

Name / Signature / Date

This Section to be Completed by the IRB

Full IRB Review Status

This Research Requires a Full IRB Review and Will Be Reviewed on: _____

This Research Has Been Approved by the IRB: _____

This Research Proposal Has Been Approved With the Modifications (see attached form): ____

This Research Proposal Has Been Denied by the IRB: _____

Approved By: _____

Name / Signature / Date

Reviewed By: _____

Name / Signature / Date