

PROPOSAL FORMAT FOR RESEARCH USING HUMAN SUBJECTS

Put your name and the title of your proposal at the top of the first page and follow the format below in preparing any proposal (exempt, expedited, full review). See Section 5 Preparing and Submitting Proposals in the 2012-2014 Policies and Procedures of the Texas Tech University Human Subjects Protection Committee for further information. The proposal narrative, recruitment materials, surveys and instruments should be submitted in **one** document, single-spaced, one-sided, with page numbers and one inch margins. Do not use staples. **Proposals will be returned to the PI if these instructions are not followed.**

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- I. Rationale:** *Include a clear statement of the problem, present knowledge relevant to the problem, and the aims of the proposed study. This section is usually no more than a few paragraphs. Include references to background literature. State the potential benefits of the work to the subjects involved and/or the importance of the knowledge to be obtained. The greater the potential risk, the more detail is needed to justify the proposal.*
 - II. Subjects:** *Describe (a) the specific population of human subjects involved (e.g., high school counselors, students enrolled in introductory Sociology classes, volunteers from First Baptist Church, etc.) including inclusion/exclusion criteria and (b) how they will be recruited (e.g., by letter, oral presentation, advertising). For research offering course credit to students, describe equivalent non-research alternatives available or refer to approved subject pool procedures. Submit as appendices the following wherever relevant: Scripts for person-to-person solicitation, and/or copies of newspaper ads, fliers, notices, etc.*
 - III. Procedures:** *(a) Describe step-by-step all procedures involving these subjects. Begin with how the subjects are recruited, what happens next, until all the steps are explained. Reference the appendix document that will be used in the procedural step. (b) Identify and assess all potential risks (physical, psychological, privacy, social, etc.), if any, with an estimate of their frequency, severity, and reversibility. Include only risks of more than negligible probability and/or severity including possible delayed effects. Finally, include any precautions that will be taken to avoid such risks (including breeches of confidentiality), and actions to be taken if these risks materialize. (c) Describe any compensation for subject participation.*
 - IV. Adverse Events and Liability:** *If the proposed research increases risks for subjects more than minimally beyond the ordinary risks of daily life, indicate (a) steps to be taken to deal with unexpected adverse events (trained personnel standing by; referral for psychological services, etc.), and (b) arrangements for handling liability for unexpected injuries. If no liability plan is offered, state that in this section.*
 - V. Consent Form:** *Consent forms normally are not required for exempt research. In this section, add N/A. For all other proposals, state "Attached" and attach a consent form covering all the relevant elements of informed consent (see Elements of Consent and the Policies and Procedures). If you want to have some or all of the elements of consent waived, please attach the blank **Waiver of Written Consent** or **Waiver or Alteration of Written Consent**. List each element to be deleted and provide a justification.*

Attachments/Appendices: *Attach recruiting materials, questionnaires, interview schedules, etc., requests for waivers of consent, a copy of the related grant proposal, if any, and other relevant information. The appendices should be labeled and placed in the order of the steps in the procedure section (Appendix A: Recruitment Material – it happens first).*