

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 the sections on Proposal Preparation, Proposal Submission, and Informed Consent in the Policies and Procedures of the Texas Tech University Human Subjects Protection Committee for further information.

I. Rationale: State the problem, the state of present knowledge relevant to it, and the aims of the proposed study. This section should clearly 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 need to justify the proposal.

II. Subjects: Describe (a) the specific population of human subject involved (e.g., patients referred by local cardiologists, 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 attachments the following as relevant: Scripts for person-to-person solicitation, and/or copies of newspaper ads, fliers, notices, etc.

III. Procedures: (a) Describe all procedures involving these subjects. (b) identify and assess all potential risks (physical, psychological, privacy, social, etc.), if any, with an estimate of their frequency, severity, and reversibility. Include 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 benefits to the subjects (including payment).

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 specific liability plan is offered, state that in this section.

V. Consent form: Consent forms normally are not required for exempt research unless they eliminate some identifiable risk. For all other proposals, 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 a separate document requesting a waiver. List each element to be deleted and provide a justification.

Attachments: 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.