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). The proposal narrative, recruitment materials, surveys and instruments should be submitted in one document, single-spaced, and with page numbers. Proposals will be returned to the PI if these instructions are not followed.

I. Rationale: Describe the problem, the state of present knowledge relevant to the problem, 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 needed to justify the proposal.

II. Subjects: Describe (a) the specific population of human subjects involved (e.g., patients referred by local cardiologists, students participating in collegiate organizations, volunteers from First Baptist Church, etc.), including the number of subjects and salient characteristics such as age range, gender, etc. (b) inclusion/exclusion criteria, and (c) how they will be recruited (e.g., by letter, oral presentation, advertising). 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 procedures involving all subjects. In the narrative, describe what the subjects do or what is done to them, the number of observations that will be made, and how confidentiality will be maintained. (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 inducement or 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 specific liability plan is offered, state that in this section.

V. Informed Consent: Describe the informed consent process including verbal interactions, written correspondence, etc. Explain how you will insure that subjects (a) understand the purpose of the study, their involvement in the study, that their participation is voluntary, and that they may withdraw at any time without penalty. Moreover, (b) demonstrate how subjects understand the extent to which their personally identifiable private information will be held in confidence. Lastly, (c) explain how you will ascertain that the subjects understand what they are agreeing to do.

Note: 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.

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. If a cooperating institution (school, hospital, prison, etc.) is involved, written permission MUST be obtained.