

IRB PROPOSAL

(Please submit all documentation electronically)

Respond to each of the following items or questions. Provide enough detail so the reviewers will be able to judge how well your study protects human subjects. Your responses must be preceded by the exact question and typed in the original order. Normally, your responses for this form will not exceed five pages.

1. Provide a brief description of the proposed study (i.e., purpose, problem to be investigated).
2. What are your qualifications for conducting the study? (i.e., what is your experience with the procedures and instrumentation to be used in this study? If a student, what is your status, and which faculty member will supervise your research and what are his/her qualifications?)
3. What are the requirements for and characteristics of the subject population? (i.e., what gender, age range, health or medical status, prisoners, institutionalized, adults, mentally handicapped, etc.)
4. How will subjects be sampled, recruited, or otherwise enlisted as participants in the study?
5. Describe, in detail, the methodology of your study. (i.e., how will the study be conducted from start to finish, as far as human subjects are concerned? Be specific about the methods, instrumentation, types of data collected, etc.)
6. Describe the personnel, materials/equipment, or other resource requirements for your study. (Identify all personnel involved in the study, their role, their qualifications, and their access to the data.)
7. How will you obtain the informed consent of the subjects? (i.e., how, where, and when will the study be explained to subjects? How will subjects indicate their consent?)
8. What are the potential risks to the subjects, and what is the likelihood and seriousness of these risks? (Risks could be physical, psychological, social, legal, etc. and may result from your experimental procedures, or your methods of obtaining, handling, or reporting data.)
9. As applicable, for each risk identified in 8, describe other methods that were considered that would reduce or eliminate these risks, and explain why they will not be used.
10. What are the potential benefits to the individual subjects and/or society as a result of the proposed research?
11. As applicable, describe how you will minimize or protect against potential risks to subjects throughout the study. (Describe emergency procedures, confidentiality safeguards, debriefing procedures, security measures for storing data, etc.) Please be sure to include information on how data will be stored and disposed of upon the completion of the project.
12. As applicable, provide the names and addresses of experts in your field (*not including the investigators*) with whom the committee members could communicate to discuss the potential risks of your procedures.
13. If appropriate, provide references to any published materials that would help the committee make a judgment regarding your procedures for safeguarding the rights and safety of your subjects.

EXPLANATORY NOTES:

1. The same questions must be addressed for all types of review. Normally, however, substantially less effort would be required to justify a study in the "exemption requested" category than would be necessary for a study which involves risk to participants.
2. If any item listed above is NOT APPLICABLE for your study, type N/A beside the item number instead of leaving the item blank.