

IRB: RESEARCH DESCRIPTION INSTRUCTIONS SHEET

In preparing the Research Description, briefly answer the questions listed below. Each response should be numbered, or labeled, to correspond to each of the items (use the underlined text as section titles). If an item does not apply to your research project, simply indicate that the question is “not applicable.” The Research Description should be intelligible to all of the IRB members, professional and lay. **PLEASE NOTE: The Research Description should not exceed 10 pages.** Use 1” Margins and 12 point Times New Roman font.

1. List your research objectives.
2. If applicable, describe past experimental and/or clinical findings leading to the formulation of your study.
3. Describe the characteristics of the subject population, such as their anticipated number, age ranges, sex, ethnic background and health status. Identify the criteria for inclusion and exclusion. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, institutionalized mentally disabled, prisoners or others who are likely to be vulnerable. If women or minorities are excluded, provide written justification.
4. Describe plans for the recruitment of subjects and the consent procedures to be followed, including how the population will be accessed, the circumstances under which consent will be sought and obtained, who will seek consent, and the method used for documenting consent. Also include a statement indicating that subjects will be asked to voluntarily enter their names into our database for future research study recruitment.
5. Describe the study design (e.g., single/double blind, parallel, crossover, etc.). Indicate whether or not the subjects will receive placebo treatment at some point in the research procedures. Also, indicate whether or not the subjects will be randomized in this study.
6. Describe the research procedure(s) that will be followed. Identify all procedures that will be carried out with each type of subject. Differentiate between procedures that involve standard/routine clinical care and those which will be performed specifically for conduct of this research project.
7. Describe any potential risks -- physical, psychological, social, legal or other -- and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.
8. Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.

9. Discuss why the risks to subjects are reasonable in relation to the anticipated benefit to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.
10. Describe the incentives (e.g., inducements) being offered to subjects for their time during participation in the research study. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms of payment. (It is IRB policy that provision should be made for providing partial payment to subjects who withdraw before the completion of the research. Monetary payments should be prorated.) Also, describe any costs which will be accrued by the subjects as a consequence of participating in the research.
11. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.
12. Describe the Data and Safety Monitoring Plan, which is the plan for the appropriate oversight and monitoring of the conduct of the research project to ensure the safety of participants and the validity and integrity of the data. The method and degree of monitoring needed is related to the degree of risk involved. Monitoring may be conducted in various ways or by various individuals or groups, depending on the size and scope of the research effort. These exist on a continuum from monitoring by the principal investigator to the establishment of an independent data and safety monitoring board for a large phase III clinical trial. Monitoring activities should be conducted by experts in all scientific disciplines needed to interpret the data and ensure patient safety. Also, where appropriate, describe the roles(s) of the inclusion and exclusion criteria with respect to the data and safety monitoring plan.
13. For research involving HIV screening and/or AIDS research, there are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Contact the Research Office at (315) 568-3867.
14. A brief CV (no more than two pages) should be included for each primary participant in the study that will permit the IRB to evaluate the researcher's levels of experience and expertise. The CV must include the status of your IRB Educational Certification. Contact the Research Office if you are unaware of your Educational Certification status.
15. A brief list of references cited should be included at the end of the research statement. These last two items (#13 & #14) are not included as part of the 10 page limit on the research description.