Form RO
Research Outline Attachment

The IRB requires a brief description of the planned research be submitted. The description should adhere to the following outline:

Rationale and Aims

This includes a concise statement of the background or rationale for the study, stressing its significance to the area of inquiry. What are the specific goals of this study? How do the methods employed pertain to reaching the goals? What, in particular, is expected to be found or learned from this study?

Methods and Procedures

A clear and full disclosure of the methods and procedures including procedures for debriefing subject are required. Any protocol submitted for review that is of insufficient clarity or lacking the details necessary for a fair and complete review will be returned to the investigator without review and with a request for revision.

Subject Population

Describe the subject population, stating specifically any reason for using a special population such as children, the mentally disabled, or other groups whose ability to give a proper informed consent is questionable.

Potential Risks

Describe carefully the potential risks (physical, psychology, social, legal, or other) and assess the likelihood and seriousness of such risks. If methods are used which create certain risks, an explanation of why these methods were used and not others is required. What alternative methods are available?

Informed Consent Procedures

Outline the procedures for obtaining informed consent, including how, where and by whom informed consent will be sought. A copy of the informed consent must accompany this application.

Safeguarding Against Risks

Describe particular procedures (e.g. proper screening or risk-prone individuals, availability of psychological or medical aid, methods of detecting illness) which will be taken to safeguard the welfare of the subjects.

Benefits and Risks

Assess the potential benefits of the investigation for the subject and for society in general. Summarize your view of the risk vs. benefit for this particular investigation.