

Main Line Health Institutional Review Board General Instructions - Protocol Preparation

The protocol should be prepared with sufficient detail and clarity so that a person not trained in the specialty field relating to the protocol will be able to understand and determine the nature, intent and scope of the project, as well as the degree of risk to the subjects involved. The protocol should be prepared according to the following outline:

1. **Purpose:** Summarize the purpose of the study and state the hypothesis which is to be tested.
2. **Subject recruitment and selection:** Provide the number of subjects to be recruited and specify their age and sex. Identify all inclusion/exclusion criteria. If subjects are excluded because of age, sex, economic status or race, the reasons must be documented. Describe any inducements which will be offered to subjects, e.g., cash payments, free hospitalization, medications or clinical testing. All advertisements to recruit subjects must be submitted for approval by the Committee. Indicate all special categories of subjects to be included, e.g., mentally retarded or disabled, minors, pregnant women, prisoner, etc.
3. **Location:** Provide the specific name of the hospital or other locations where the research will be conducted.
4. **Background:** Describe succinctly and clearly the past findings which led to the plan for this research. A summary of the relevant literature in the area and reports of previous studies can be included. This background information should include complete information available to the Principal Investigator from the sponsor or other sources regarding pre-clinical or clinical investigations of the test article, clinical modality or drug.
5. **Research Design:** Prepare an orderly scientific description of the intended procedures as they directly affect the subject and include:
 - a. the number and estimated length of hospitalizations, length of time for various procedures (e.g., interviews, completing questionnaires), frequency of repetition, randomization, and any manipulation which may cause discomfort or inconvenience;
 - b. doses and routes of administration of drugs and the amount of blood to be withdrawn;
 - c. plan for follow-up;
 - d. if there is a point at which the study procedures may be discontinued, a statement of how this will be determined and monitored, including measures which will be taken to treat side effects or to handle or refer problems identified during the study; and;
 - e. a copy of any questionnaires or rating scales to be used. If the questionnaire is not yet drafted, the PI should submit to the Institutional Review Board a summary of types of questions or draft questions for review.
6. **Risk and Benefits to the Subject.** Provide a comprehensive statement regarding risks and benefits which shall:

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- a. describe and assess any potential physical, psychological, social, economic, monetary, legal or other risk, including risk of placebo, washout, or discontinuation of other drugs if applicable;
 - b. assess the potential benefits to be gained by the individual subject, as well as benefits which may accrue to society in general as a result of the planned work; and;
 - c. describe procedures (including confidentiality safeguards) for protecting against or minimizing potential risks.
7. **Protection of Subject Confidentiality.** Describe what information about this project will be kept as a permanent record. Indicate how, when and to whom information pertaining to this research will be disseminated. Specifically describe any circumstances in which subject-identifiable data may be disclosed to persons or organizations not involved in this research.