

GUIDELINES FOR DESIGNING A CLINICAL STUDY PROTOCOL

(based on International Conference on Harmonization, GCP Guidelines for Clinical Trial Protocol development)

To draft a sound scientific design of a clinical research study, the medical writer at the TGH, Office of Clinical Research recommends that the following information should be included in a research protocol. It will help facilitate the application submission process and study approval from the Office of Clinical Research and IRB.

Study Summary:

Study summary should include the following:

- Protocol title (*The title on related IRB submissions (e.g., applications for new study, changes in procedure, research progress reports) must match the title of the protocol*)
- Study phase
- Duration of the study
- Methodology
- Study site
- Approximate number of subjects
- Name, title, address, and telephone number of the PI, Co-PI, sponsors and study coordinators
- Investigator's affiliation

List of Abbreviations:

Provide a list of abbreviation used in the study protocol.

Background Information/Significance:

- Name and description of the investigational product, and in case of retrospective reviews, justification for the chart and medical record reviews.
- Summary of results from prior clinical studies and clinical data to date.
- Human subjects risks and benefits.
- Description of the population to be studied.
- Description and justification for the dosing regimen and treatment period.
- A paragraph stating that the clinical study will be conducted in compliance with the protocol, SOPs and the federal, state and local regulations.
- Citations from the references and data relevant to the study that also provides background for the trial.

Objectives/Rationale/Research Question:

- Include a detailed description of the primary and secondary objectives and the purpose of the study and clearly state your research hypothesis or your question.
- Discuss the project's feasibility.
- Give details of resources, skills and experience to complete the study.
- Include any pilot study information.

Clinical Study Design:

- Primary and secondary endpoints, if any, to be measured during the study.
- Include the information that is needed to answer the research question.

- Include the study design e.g. single, double-blind, observational, randomized, retrospective etc. A schematic diagram of the study design would be helpful.
- Include the amount of dosage, dosing regimen of the drug, packaging and labeling of the experimental drug.
- Explain how the study drug will be stored and dispensed.
- Include the expected duration of the study and subject's participation and a description of the sequence and duration of all study periods.
- Include any follow up visits.
- Describe when a subject's participation in the trial may be discontinued.
- Maintenance of randomization codes and confidentiality.
- Describe the potential risks and steps taken to minimize the risks.
- Identify possible benefits of the study.

Inclusion and Exclusion criteria of the Subjects:

- Include subjects inclusion criteria.
- Include subjects exclusion criteria. Women of childbearing potential may not be routinely excluded from participating in research, however, pregnant women should be excluded unless there is a clear justification to include them.
- Include enrollment of persons of diverse racial and ethnic backgrounds to ensure that the benefits of the research study are distributed in an equitable manner.

Informed consent form process:

- Provide information about the regulatory requirements of the consent form and which languages will be used.
- Include a discussion of additional safeguards taken if potentially vulnerable subjects will be enrolled in the study e.g., children, prisoners, cognitively impaired and critically ill subjects.
- Specify Code of Ethics under which consent will be obtained.
- Include a copy of the proposed informed consent along with the protocol.

Adverse Event Reporting:

- Describe your plan to report any adverse event.
- Anticipated adverse events should be clearly documented.
- Identify the type and duration of follow up and treatment for subjects that experience an adverse event.

Assessment of Safety and Efficacy:

- Be specific about the efficacy parameters.
- Include the methods and timing for assessing, recording, and analyzing efficacy parameters.
- Specify the safety parameters.
- Record and report properly all the adverse events and inter current illnesses.

Treatment of Subjects:

- List all the treatments to be administered including product's name, dose, route of administration, and the treatment period for subjects.

- Include all medication permitted before and during the clinical trial.
- Include the procedures for monitoring subject compliance.

Data Collection Plan:

- Define the type of data collection instrument that will be used and list all the variables.
- Specify if computerized databases will be used.
- Identify what software will be used.
- Explain precautionary steps taken to secure the data.

Data Access:

- Inform who will have access to the data and how the data will be used. If data with subject identifiers will be released, specify the person(s) or agency to whom the information will be released and the purpose of the release.
- Address all study related monitoring, audits, and regulatory inspections.

Statistical Methods:

- Describe the statistical methods in detail.
- Include the number of subjects you are planning to enroll. For multi-center studies, include the total number of sites expected and the total number of subjects to be enrolled across all sites.
- Provide the rationale for the sample size, the calculations on the power of the trial and the clinical justification.
- Procedure of accounting for missing, unused and spurious data.
- Procedures for reporting deviations from the original statistical plan.
- Include the selections of subjects to be included in the analyses.

Conflict of Interest:

Identify and document clearly any consultative relationship that the principal or co-investigators has with a non-USF entity related to the protocol that might be considered a real or apparent conflict of interest.

Publication and Presentation Plans:

List any meetings or conference you will be presenting the data and the results of your study.

Timeline:

- A short paragraph stating when you plan to start and complete the study.
- Include a description e.g. subjects enrollment within a month, data collection within 6 months etc.

References:

List all the references used in the back ground section at the end of the protocol.