

Research Study Protocol Template

*Used with the permission of Dr. Sadaf Aslam

Instructions

This protocol template is a tool to facilitate the development of a research study protocol specifically intended for the investigator initiated studies. It contains sample text to assist investigators in answering the questions reviewer may have. It should be modified based on the type of study design to include any other information which is required by the IRB.

Protocol template instructions and samples are in *italics*. Delete the italicized text and the instruction after you complete each section. Include all elements even if you are conducting a retrospective chart review.

Study Protocol Title:

Be consistent with the Title throughout your application and the regulatory documents

List of Abbreviations:

Use commonly used abbreviations and acronym.

Principal Investigator, Research Team, and Study Site:

Principal investigator:

Co-Investigators:

Research team and contact Information:

Study site:

Research Synopsis:

This should include a brief description of the study design, population and duration of the study

Background and Significance:

Overall it's a justification for conducting this study based on existing knowledge and your research question. It's like telling a story-start with what is known and unknown based on the literature search and then come to your research question and how would you answer that question.

Describe the disease including incidence, prevalence and any existing interventions

Provide a summary of previous pre-clinical studies, relevant clinical studies

Include references with citations from the literature

Objectives:

These should be defined after the theoretical framework has been developed. The sequence should be clear between the primary question and possible responses to the questions or hypotheses.

Primary Objective

Include the details of your primary objective which is your main purpose of performing this study and should be focused on one question). This section is usually not clear. Make it simple and easy to understand

Sample Text:

To evaluate the efficacy of a.....

To assess....

Secondary Objectives

Include secondary objectives which can be two or three can be dependent or independent of the primary objective.

Study design/methodology:

- Include the description of study type, for example, double-blinded, placebo-controlled, open/off label, parallel or crossover design, randomized, number of study arms, prospective, retrospective, or observational. Type of study and design should be decided on the basis of proposed objectives and the availability of the resources. If it's a randomized controlled trial,*

randomization process should be described in detail. The methodology section explains the procedures that will be used to achieve the objectives.

- In this section the definition for the outcomes variables used should be specified in detail, along with the type of variables and the ways to measure them. In case of prospective cohort studies, provide details for how long you will follow the patients. Details of the methods and procedures should be included. It's always helpful for the reviewer to make a flow chart with each step of the study and duration.*
- What kind of data will you be collecting to measure your primary and secondary outcomes? What instruments/tools will you be using?*
- Make sure this section includes outcome measures based on your primary and secondary objectives. Each objective should have a corresponding discussion in this section as to how would you measure that outcome.*

Study Population:

Details of the population to be included in the study

Inclusion /Exclusion Criteria

Any inclusion of vulnerable population? 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 subjects with diverse racial and ethnic backgrounds to ensure an equitable selection.

Study drug /Interventions:

In case of retrospective chart review, or any observational study, attach any survey, instrument, questionnaire which will be used and a data collection sheet

Formulation, packaging, and labeling of the study drug or device

Address issues with the study drug storage and stability

Provide details of the preparation, administration, and dosage of study drug/intervention)

Study Schedule:

Include a projected start and an estimated end date.

Provide the total length of time participants will remain in the study or will be taking drug including the follow up period. It is convenient for the reviewer to see the events of the study schedule or duration in the form of a flow chart. Include screening, enrollment, active dosing phase, follow-up visits, and final study visit.

Adverse Event Reporting:

Definition of an Adverse Event (AEs) & Serious Adverse Event (SAEs) should be provided

Include methods and timing for assessing, recording, and managing safety parameters

Also, include how you will report these procedures and stopping rules for a study participant.

Statistical Analysis Plan:

What do you plan to analyze from the data you collect? Consult a biostatistician before you finalize your protocol.

Sample size determination

What sample size will you be able to get and if your suggested samples size has enough of power to deliver the significant results? Include the number of subjects you are planning to enroll. Provide the rationale for the sample size, the calculations on the power of the trial and the clinical justification. In case of chart review provide justification for including any number of charts you will be reviewing unless you are conducting a proof of concept study or pilot study.

Include plan of accounting for missing, unused and spurious data

Informed Consent Process:

Provide information about the regulatory requirements of the consent form and which languages will be used. For Spanish speaking population a Spanish consent form should be included. The language and writing of an informed consent is usually at a 6th grade level.

Include a discussion of additional safeguards taken if potentially vulnerable subjects will be enrolled in the study for example pregnant and lactating women, children, prisoners, cognitively impaired and critically ill subjects. Templates are available at the USF/IRB website

Privacy and confidentiality:

Sample language: Participants' names will be kept on a password protected database by the investigators, and will be associated only with a study identification number for this research. There are no patient identifiers. All data will be entered into a computer that is password protected. Data will be stored in a locked office of the investigators and maintained for a minimum of three years after the completion of the study.

Some institutions have different time frame for the storage of data. Check institutional SOPs

Risk/Benefit:

Risk to participants:

Identify any risks involved while conducting the study

Benefits to Participants

Include any benefits to the participant or to the overall research field

Sample text: This study does not present the prospect of direct benefit to the participants. However the study does provide an opportunity to gain a better understanding of

Study Timeline:

Briefly state the stages of your study for example,

Stage 1, screening, enrollment, review of medical records ----4-6 months

Stage 2, treatment phase

Stage 3, data collection and data analysis

Stage 4, presentation and publication...

Data Safety Monitoring:

Monitoring is an ongoing review of the adherence to the study design.

Plans for assuring that any action resulting in a temporary or permanent suspension of the study is reported to the IRB and to the Office of Clinical Research

The PI is responsible for reporting any reasons outside the planned study design such as noncompliance with the protocol or when administrative reasons delay the study. A greater than minimal risk study requires an establishment of a Data Safety Monitoring Board (DSMB).

Conflict of Interest:

Clearly document any consultative relationship that the principal or co-investigators has with a non-USF entity related to the protocol that might be considered an apparent conflict of interest. Depending upon the type of conflicts, these can be managed accordingly.

Publication and Presentation Plans:

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

References:

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

Endnote is a software tool for publishing and managing bibliographies and is used frequently for citations and managing endnote libraries.