

# Study Protocol Template

(Chart Reviews)

## **Instructions:**

This protocol template is a tool to facilitate the development of a study protocol specifically designed for the investigator initiated studies. It contains sample text to assist investigators in answering the questions reviewers may have. Protocol template instructions and samples are in *italics*. Please delete the italicized text and the instructions after you complete each section.

It is recommended that section headings in the protocol template should not be deleted. It facilitates the review process. If the heading does not relate to your study insert N/A.

Start from here:

## **Study Protocol Title:**

*Be consistent with the Title through out your application, protocol and the regulatory documents*

## **Table of Contents:**

## **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**

### **Study Title**

*Enter the full title*

### **Study Population**

*Include a brief description of the population such as health status, gender, age, etc.*

### **Study Design**

*Present an overview of the study design for example, retrospective chart review, data or specimen collection etc*

### **Sample Size**

*Include total number of patients or charts for the study including other sites.*

### **Study Duration**

*Length of time to review charts, data collection, and analysis till the completion of the study*

### **Primary Objective**

*Include primary objective and outcome measures*

### **Secondary Objectives**

*Include secondary objective and, outcome measures*

### **Background and Significance:**

*This section is based on your research question. How are the possible answers to the question explained and defended? What are assumptions and relationships? What are the working hypotheses? Justification of your conducting this study based on existing knowledge and your research question.*

*Describe the disease including incidence. Provide a summary of previous pre-clinical studies, relevant clinical studies, or any epidemiological data if available*

*Include references with citations from the literature.*

*In the last paragraph state the main purpose of the study summarizing all the information provided in your background section.*

### **Objectives:**

*These should be defined after the theoretical outline has been developed. The sequence should be clear between the primary question and possible responses to the questions or hypotheses. The objectives are the intellectual activities that the investigator will perform throughout the research study.*

### **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), outcome measures and method by which outcomes will be determined.*

*Sample Text: To evaluate the efficacy of antibiotics in the treatment of acute bronchitis*

### **Secondary Objectives**

*Include secondary objectives which can be two or three can be dependent or independent of the primary objective, outcome measures and method by which secondary outcomes will be determined.*

*Sample text: To assess patients overall change in symptoms and return to daily activities after 2 weeks of antibiotic treatment*

*To evaluate management and treatment factors as potential predictors of outcome.*

### **Study design/methodology:**

*Include the description of study type, for example prospective data or specimen collection, retrospective, or observational, survey, or questionnaire*

*Type of study and design should be decided on the basis of proposed objectives and the availability of the resources.*

*The methodology explains the procedures that will be used to achieve the objectives. In this section the definition for the variables used should be specified in detail, along with the type of variables and the ways to measure them.*

*Example text: This is a retrospective chart review of patients treated for .....with..... .*

*What kind of data will you be collecting to measure your primary and secondary outcomes?*

### **Study Population:**

*Details of the population to be included in the study*

#### **Inclusion /Exclusion Criteria**

*What are the criteria for including or excluding any particular population?*

*Include enrollment of subjects with diverse racial and ethnic backgrounds to ensure an equitable selection.*

### **Study Duration/ Study Timeline:**

*Briefly state the stages of your study for example,*

*Stage 1, review of medical records ----4-6 months*

*Stage 2, data collection and data analysis*

*Stage 3, presentation and publication...*

*Include a projected start date.*

*Provide the total length of time and include an approximate end date of the study.*

*It is convenient for the reviewer to see the events of the study schedule or duration in the form of a flow chart.*

### **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 charts you are planning to review. For multi-center studies, include the total number of sites expected and the total number of subjects to be included across all sites.*

*Provide the rationale for the sample size, the calculations on the power of the trial and the clinical justification.*

*Include plan of accounting for missing, unused and spurious data*

### **Informed Consent Process:**

*In case of retrospective chart reviews an application for the waiver of consent form can be filled out depending upon the IRB criteria of review (expedited, exempt, full board). In case of a prospective data collection, include 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 6<sup>th</sup> grade level.*

*If potentially vulnerable subjects will be enrolled in the study for example pregnant and lactating women, children, prisoners, cognitively impaired and critically ill subjects, include a justification.*

#### ***Privacy and confidentiality:***

*Sample language: Human subject's names will be kept on a password protected database and will be linked 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 any direct benefit to the participants. However the study does provide an opportunity to gain a better understanding of .....*

**Data Safety Monitoring:**

*Monitoring is an ongoing review of the study throughout its duration.*

*Any action resulting in a temporary or permanent suspension of the study should be 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 non-compliance with the protocol or if there is any delay in the initiation of the study due to administrative reasons.*

**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 and Reference Manager are the software tools for publishing and managing bibliographies and are used frequently for citations and managing your own libraries.*