

## Protocol

*We recommend anyone interested in doing a clinical research project contact the CRI at the onset of the process. We can help you design a study that can be done in a manner that facilitates execution of the study and publication of its results. Consulting the CRI biostatisticians is also highly recommended prior to commencing the study. We suggest you use the headings provided below as a template.*

*When the protocol has been completed, the CRI can do the submission to the IRB and provide assistance you might need in the conduct of the study including consenting and enrolling subjects, taking samples and recording data. The CRI biostatisticians can analyze the data, and the CRI can assist you in writing the publication.*

### **Instructions/guidance for each section is provided in red**

**TITLE:** The title should inform the reader as to what the study is designed to test. Consider using a title that captures the heart of the project. Indicating if the study is prospective or retrospective as well as the study population should be considered. You can change the title when submitting the paper for publication should you wish to do so.

**INVESTIGATORS:** List all persons who will have any role in the study. Please include highest degree, rank if applicable and institutional affiliation. If asked, you should be able to justify inclusion of listed personnel. FYI---They must be listed on the protocol approved by IRB in order to help with the study.

#### **Abstract/Project Summary**

Provide a succinct and accurate description of the proposed research. State the purpose/aims. Describe concisely the research design and methods for achieving the stated goals. This section should be understandable to all members of the IRB, scientific and non-scientific.

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**AIMS:** The AIMS briefly describe WHAT you will do in the study.

**OBJECTIVES:** Describe briefly HOW you will get your AIMS answered.

#### **INTRODUCTION / BACKGROUND / SIGNIFICANCE:**

This does not need to be extensive but must indicate why the research question is important, what is known about it from the literature and how your project will help expand knowledge. Usually two to 3 paragraphs should suffice. Provide pertinent citations which can be listed at the end of your proposal.

**HYPOTHESIS:** This is the BRIEF statement of what the investigator believes will be the answer to the question he/she is asking. The question will have a yes/no answer.

**METHODS:** Be specific such that your study is reproducible. This includes details of any assay methodologies, measuring instruments/tools. The proposed statistical analysis is also generally provided in this section as indicated below

**Type of study:**

Retrospective vs prospective.

Hypothesis-driven vs Observational vs Pilot study.

**Subjects:** Include such information as:

Gender

Age

How will they be recruited?

Provide recruiting communique so IRB can peruse it

Recruited from where

Randomized and how?

**Inclusion criteria:** List specific criteria each subject must have such as:

Age range

Diagnoses

Lab ranges

Radiology findings

Other ancillary findings that have to be present

**Exclusion criteria:** List those conditions that would confound the study if a projected subject were enrolled. Such as:

Pregnant or breastfeeding females

Limited life span

Inability to give consent

Psychiatric diagnoses

Inability to follow up

6 Previous intervention that could influence your results

Current medications or OTC supplements that could impact your study

Note: working with prisoners, kids, pregnant women and individuals with mental illness requires extra steps.

**Site of study:** For example, the Family and Internal Medicine Clinics at TTUHSC or University Medical Center Hospital, Lubbock, TX.

**Design:** Consult with the biostatistician about the design as well as the statistics suitable for the design. Remember to provide enough detail so that someone else can EXACTLY duplicate your study and hopefully confirm your results.

Include such information as:

How many groups and how many subjects per group?

What will be the treatment for each group, and how will it be administered?

How long will the intervention last?

Will there be a pill count if subject responsible for taking meds?

If blood will be drawn for labs – provide methodology, reproducibility of assay

Will blood samples be drawn, from where, how many tsps, when?

What measurements will be made, how often & for how long?

If equipment will be used provide manufacturer

**Study visits/Roles of subjects:** Describe what will occur at each study visit, what data will be collected. Also consider providing this as an appendix. For example:

Visit 1: informed consent, blood for CBC, urine for urinalysis and pregnancy test, echocardiogram

Visit 2: Occurs within 3 weeks of visit 1. Blood for lab work, echocardiogram.....

**Materials, instruments or measurements:** What are you going to use to assess your patients or get information about the participants? Cite references where necessary to validate your choice. Will you be storing blood in the hope that you can later return and analyze them based on your current study results? If so at what temperature would you want them stored at and site of storage?

**Data Sheet:** This is typically an Excel spreadsheet that lists every data point you want to collect on each participant. Construct the data sheet using binary system entries where possible. Check with the biostatistician who will do the analysis of the data.

**Outcomes:** List the primary and secondary outcomes-the data elements that will tell you if you answered your questions, specific aims.

**Analysis:** Describe the statistical analysis to be used with justification. Note that studies can also be classified as Observational, seeking to reveal specific associations.

Some studies can be considered Pilot studies done to demonstrate the potential value of doing the complete study. This might be necessary due to complexity of the study, lack of sufficient available subjects, a high cost for the study or need to demonstrate potential in order to obtain sufficient funding. Protocol should indicate that it is a pilot study and why it is being done. A biostatistician should be consulted.

**Justification for Sample size:** Need minimum and maximum number of charts or patients you expect to use/see--- and an explanation of how you came to those numbers. Pilot study? Did you do a power analysis?

**Risks:** Describe the risks, what will be done to minimize them and what will be done if problem encountered. Remember that there is always risk, even if only loss of confidentiality.

**Benefits:** (To participants or the public at large) The objective of most clinical studies is to obtain results that will ultimately benefit the general population. Occasionally, subjects in any study might benefit directly but this is usually not expected.

**Confidentiality:** Describe your methods for handling this (de-identification, code list) and what is your method of securing the data in a confidential manner. Study documents will be kept at least 3 years then destroyed.

**Monitoring:** IF this is needed, it will be developed in conjunction with you and can be submitted by the CRI.

**Reimbursement:** Subjects can be given a reasonable stipend. The amount of the stipend should not be viewed as an inducement to participate.

**Funding:** State if your department is funding this study, or you got funding from elsewhere.

**Consent Form:** IF this is needed, CRI can help you develop and submit this.

**Acknowledgements:** Any help received from the CRI, other faculty,

**References:**