**Project Title**

This should be specific and precise. It should indicate what one intends to do, find out, or evaluate, and how this will be carried out. It should not be overly long (never more than 2 to 3 lines) and should not be ambiguous.

**Principal Investigator and Co-Investigator Information**

Include the following:

* Name
* Title
* Organization affiliation
* Phone number
* Mailing address
* Email address

**Research Question/Hypothesis**

This should be well-defined, important, relevant and answerable by your proposed methodology.

**Objectives**

Research objectives are measurable goals, or outcomes, to be achieved by conducting the research. The primary outcome will be specifically what is to be accomplished by the intervention you are proposing. Secondary outcome(s) are additional effects that are believed to be a result of your intervention.

**Background to Research Questions**

This background is an essential part of the proposal. In this section, you are attempting to convince the reader that your research question is valid and there is justifiable cause for conducting this research study, and that this research worth the risk exposure.

The background should include the following:

* Why does this research question need to be addressed?
* Does it relate to a common emergency or family medicine problem?
* Is there a substantial prevalence of morbidity or mortality? (Include data)
* Are there deficiencies in our current knowledge of this topic? (Include data)
* Summarize any preliminary research that has been done, if applicable
* Literature review: What is already known about this subject? Summarize findings of previous studies, including key references.

**METHODOLOGY**

**Study design**

Summarize the study design in one short sentence. (EX: The \_\_\_\_\_\_\_\_\_\_ study is a prospective cohort study designed to test\_\_\_\_\_\_.) No further detail is required unless an explanation is necessary in the case of using an unusual choice of design.

**Intervention**

The intervention should be described in detail, including a justification of how this intervention is appropriate in relation to the research question and the existing literature.

(Include the following statement at the end unless it doesn’t pertain: All study-related materials will be destroyed after official closure has been confirmed by the IRB.)

**Setting**

The research setting should include where the study is going to be conducted. Indicate all of the areas that any study-related activity will be carried out.

**Expected Start Date**

If unknown, just state “upon IRB approval”.

**Duration of Study**

Describe the time frame that the study will last. This should include how long patients can be enrolled, the overall length of participation, and how long data analysis is anticipated to last. For a retrospective study, include the specific dates that will be reviewed.

**Study Subjects**

The study subjects section details the specific population to be studied. Include the following:

* The population being studied
* The maximum number of study subjects
* Criteria a patient must meet in order to be eligible for the study
* Factors that will disqualify them from being an eligible participant.
* Whether there is a need for patient consent. If consent is required, the type of consent must be specified, and how it will be obtained (written, verbal consent, etc.). A copy of the written consent, or verbal consent script, should be included in the appendix.
* If applicable, justification for use of special subject population (EX*:* children or prisoners)

**Equipment/Supplies/Services**

If applicable, detail any services, supplies, or equipment needed to carry out this research study. Indicate whether they will be provided by CHRISTUS Spohn or by you, the PI.

**Data Collection**

Include the following:

* What specific information is going to be looked for/collected?
* How this is going to be done (EX chart review, patient survey)?
* Instrument/Tools used to collect data
* Who is going to perform the data collection?

**Data Analysis**

Include the following:

* Who will be analyzing the data?
* The computer package to be used in the data entry and analysis (EX: MS Excel, SPSS)
* The type of statistical tests to be used (EX: regression analysis, 't' test)

**Data Management**

Include the following:

* Where the collected data is going to be kept?
* How the collected data is going to be managed (EX: computerized spread sheet, hard copies)?
* How the information will be kept confidential? Be very detailed in this section. (EX: The data will be kept in a locked file cabinet in the locked PI’s office; The data will be kept in a password-protected computer database that only the PI or co-PI’s will have access to)?
* If known, the format of how the results will be presented (EX: Tables,Pie charts, Histograms, Line graphs)?

**Identified Risks/Ethical Considerations**

Include any identified risks or potential ethical issues that this study may present, and how these issues will be addressed.

**Benefits of Proposed Research to the Subjects and Others (significance of your study)**

This section should detail an accurate description of the possible benefits, if any, for the study participants. Clearly state if participants will or will not receive compensation. If participants are receiving any possible form of compensation, this compensation should be detailed.

Also include the societal benefits of the study. Examples of societal benefits can include contributions to scientific knowledge and medical progress, or potential benefits to future patients.

**References**

List containing all cited literature, in an internationally accepted format (EX: APA, AMA, MLA)

**ATTACHMENTS**

**Survey (if using a survey)**

**Data collection spreadsheet**

**Consent forms if needed**