**Every human subject research study must have a protocol. When a study is sponsored by industry, a protocol is typically provided by the sponsor. If a protocol is not provided by the sponsor, or a study is initiated by the Principal Investigator (PI), the PI must create the detailed protocol for the study. This is a guide that can be used when creating a protocol. It includes the different areas that should be included. It is not meant to be in question format with answers, but rather a document that addresses the different areas.**

**PROTOCOL**

**Study Title**

**Name, title, department of Principal Investigator (PI) (**A TTUHSC EP PI must have a faculty appointment and be a full-time (greater than 50%) employee of TTUHSC EP (compensated).

**Name, title, department affiliation of any co-investigators**

**Version**

**Abstract**

**Hypothesis**

**Background (literature review)**

**Specific Aims**

**Significance of this study (why is it important, what new information will it provide?)**

**Study Design & Methods (include the following information):**

1. **Subjects**:
2. Describe the method of identifying and recruiting subjects and any screening that may take place
3. Describe the informed consent process and timing of obtaining consent. If at any time it will be virtual with electronic consent, this must be indicated and explained in detail
4. If non-English speaking persons will be enrolled, state the informed consent process for enrolling the subjects, including who will conduct the consent interview, translated documents, etc. Exclusion of non-English speaking subjects from research requires ethical and scientific justification
5. Indicate the population of subjects potentially able to participate in this study
6. Indicate the number needed to reach a conclusion
7. List the inclusion/exclusion criteria
8. Vulnerable populations-Provide justification and precautions for inclusion of any vulnerable populations indicated
9. Define how long each subject will be studied, how many visits, timing of the visits, etc.
10. Describe the sites where the study will be done
11. Describe the risks
12. Describe the possible benefits to subjects (if none, state none)
13. Describe any compensation given to subjects and whether it will be prorated
14. Describe the confidentiality measures that will be in place to protect the data and PHI
15. **Describe the following aspects of the study design**:
16. Proposed study groups with number/group and treatments/group
17. Describe the method used to determine the number of subjects needed
18. Describe how you determined that this number of subjects could be recruited
19. Method of randomization
20. Schedule of events (i.e. control vs. treatment, number of visits)
21. List of Key Variables or Measurements to be done
22. Assessment of subject safety and development of a data and safety monitoring plan
23. Create and attach your data collection form(s)
24. Methods of data analysis (statistical analysis)

**Guide for Completing Each Section (do not include in the final submission)**

1. **Hypothesis**: This defines the question you are asking, and what you propose based on an observation or something that you have read. This would be directed either at extending the knowledge base or providing information that fills a gap in the knowledge base. In those instances your hypothesis should define an outcome for a specific comparison, and there should be a yes/no answer to the question you are posing (the null hypothesis).
2. **Literature Review**: In this section, briefly describe the key findings from relevant supporting literature and the limitations.

Your hypothesis should have a reasonable basis that is supported by previous observations related to your proposal. These should be documented by a review of the literature from peer-reviewed journals that are respected within your field. In those instances, when your hypothesis contradicts current opinion, cite the aspects of the methodology of other studies that you think might have led to erroneous conclusions. Keep the aims/objects few and specific. Avoid having multiple aims.

1. **Objectives, Specific Aims, and Hypothesis**: State the objectives and specific aims of the study based upon the questions which have gone unanswered or have been poorly addressed by previous studies.

Objectives can be short- or long term and should be stated as “to do” something (i.e. to determine, to measure, to demonstrate, etc.). Avoid using words such as explain, discuss and illustrate, which are ambiguous in describing your objectives. The specific aims describe and define exactly what you will do in this proposal. There should be a specific outcome that can be tested and will be measured.

1. **Significance of the Proposed Study**: State why the proposed study is innovative and how the conclusions to be drawn will contribute to our knowledge or enhance clinical practice. This should be supported by the citations discussed in the literature review.
2. **Study Design**: State the overall study design. Your experimental design should follow the best statistical analysis that will allow you to monitor the outcomes you derive and to make the comparisons you are interested in relative to your hypothesis. Then ask the following questions. What will be the groups, treatment vs. control? What will be the independent variable and what will be the dependent variable? What outcome(s) would you like to measure and how can you best do this? What will be the time frame in terms of a control period, the experimental period and a possible “recovery” period? How many subjects do you need for your statistical analysis, and how can and will you obtain them? This will involve a power analysis. What other factors must you control for?
3. **Data Collection Protocol**: State where and how you will obtain your data. In order to test the hypotheses, you must have data obtained directly by observation, by measurement or by surveys or availably through existing records (i.e. clinical charts). Develop a system for recording data. It can then be entered into a spreadsheet or other data management system.

Remember that there are legal requirements for confidentiality, meaning that any subject/patient identifiers must be separated from the data by use of a coding system. The code key must be stored securely and destroyed when data analysis has been completed. Coding also permits the investigator to perform a double-blinded study which is an important design component preventing any chance for results to be influenced by a bias.

1. **Statistical Analysis**: Provide brief explanations of the tests or analyses that will be used to determine if the results are meaningful. The type of analysis to be used must be decided upon in conjunction with designing the protocol. The experimental design depends on appropriate statistics to evaluate the outcomes and to be able to test each hypothesis.