# PROTOCOL

*Fill in the following sections. If this application relates to a research proposal, please still answer the questions below and indicate the page number in the proposal that corresponds to the given answer.*

1**. Title**:

2. **Background & Introduction**:

*(Annotate with references, all references should be listed under #19)*

3. **Problem Statement**:

*(Clearly state what problem your study is intended to address)*

4. **Study Justification**:

*(Why should your study be done? Please include any benefits that you anticipate to the hospital or patient care)*

5. **Objective(s)**:

*(What do you hope to achieve with this study?)*

6. **Research Question(s)**:

*(What specific questions will this study answer?)*

7. **Study Design**:

*(Is the study quantitative or qualitative? What type of study is this? Examples include retrospective or prospective, cohort or case-control, phenomenology to name a few)*

8. **Study area and period**:

*(List all institution(s) where study will be done. Note that approval is required from all institution(s) where it will be conducted. Also include the department involved)*

**9. Sample size determination:**

*(This should be a statistical calculation for quantitative studies or referenced sample size for qualitative studies- supported by published data)*

**10. Sampling method:** (check if randomization used \_\_\_\_)

**11. Study Population, Inclusion & Exclusion criteria:**

*(Include how subjects will be recruited and attach or include any flyers or other types of promotion. Inclusion criteria typically include demographic, clinical and geographic characteristics. Common exclusion criteria include reasons why participants might be lost to follow up, provide inaccurate data or comorbidities that can bias the study)*

**12. Data collection method:**

*(How will data be collected?)*

**13. Data Entry & Protection:**

*(How will data be entered? Specifically describe how confidentiality and anonymity will be maintained, and how data will be stored and/or disposed of during and after the study.)*

**14. Data Analysis:**

*(Provide the plans for data analysis, statistical or otherwise. Qualitative data analysis should be supported by a reference)*

**15. Dissemination of Findings:**

*(How will the results of this study be communicated back to stakeholders both locally and internationally?)*

**16. Ethical Considerations:**

*(Address if any of the study population is considered vulnerable, such as children, minors, pregnant women, economically and educationally disabled, prisoners, etc. Please also include the Safety Monitoring Plan for the study)*

**17. Work Plan:**

*(Gantt chart is recommended for this section)*

**18. Source of Funding and Budget:**

*(A table for the budget is recommended)*

**19. References:**

**20. Study tools**

*(All tools, for example questionnaires, surveys, REDCap forms, interview guides, focus group discussion questions, etc. must be attached)*

21**. Informed Consent**

*(Insert or attach any informed consent forms, being sure to pay attention to additional instructions found in #4 of the checklist below)*

Principal Investigator’s Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_