Please complete this protocol template to facilitate a thorough review of the study by CSOR staff. Fill out as much as possible and omit sections that do not apply. Please reference the guidelines for working with our biostatisticians and epidemiologists while creating the guidelines.

# Part 1

## Administration (Please enter all applicable fields.)

|  |  |
| --- | --- |
| Project Title |  |
| Principal Investigator |  |
| PI Email & Phone |  |
| Co-Investigators (list first and last names) |  |
| Study Coordinator |  |
| Study Coordinator Email & Phone |  |
| IRB Protocol Number |  |
| Funding Source |  |
| Proposed journal and/or academic meeting |  |
| Target audience of publication (e.g. surgeons, schools, parents/families) |  |
| PI Conflict(s) of Interest |  |

# Part 2

## Background

1. What is the problem that needs to be solved?
2. What are the gaps in previous research/knowledge?
   1. What do we already know?
   2. What don’t we know?
   3. How would knowing this help us to improve clinical care, reduce costs, etc.?
3. In 1-2 sentences, please state the research question and/or hypothesis(es).

Please list the study objectives below. Statements should include outcome measures and the method by which outcomes will be determined (add additional, if needed):

*Example: “To evaluate the efficacy of antibiotics in the treatment of acute bronchitis”*

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

**\*Please reference at least 2-3 relevant articles below or attach them with your submission.**

## Methods (This section will explain what procedures will be used to achieve study objectives. Please consult one of our statisticians/epidemiologists as needed.)

1. What type of study is this? (e.g. case-control study, cohort study, randomized, double-blinded)
2. Why was this particular type of design selected?
   1. If this is a retrospective study, what dataset, database, or registry will be used?
3. Eligibility criteria:
   1. Inclusion criteria. What characteristics, traits, procedures, etc. of patients will allow them to be included?
   2. Exclusion criteria. What characteristics, traits, procedures, etc., will exclude patients from the study?
4. Data Collection: Please describe the data collection process in steps. (Note: Before data collection begins, a definition of all variables should be finalized by all investigators.)
   1. How will the list of patients/study subjects be assembled?
   2. How and by whom will primary data be collected and/or secondary data extracted?
   3. How many patients are anticipated/required to sufficiently power results?
5. Intervention (if applicable)
   1. What procedures or groups of patients are to be compared?
6. Outcome variables (or dependent variables).
   1. What is the characteristic(s) or outcome(s) that is considered the endpoint for this study?
7. Predictor variable (or independent variables).
   1. What patient characteristics, traits, procedures, or therapies are to be explored that may correlate with or predict the endpoint?
8. Describe the analytic plan including power/sample size calculation, if appropriate.
9. Please list any additional references below.

## Timeline

## (Please suggest a timeline for the proposed project. Include deadlines or approximate days/weeks/months to completion.)

Funding Notice

IRB Application/Approval

Data Collection/Analysis

Abstract Preparation

Poster Preparation

Manuscript Preparation