**Study Protocol Outline**

1. **Title Page**

* protocol title, principal investigator, co-investigators, date

1. **Abstract *(optional)***

* brief one-page summary of proposed research

1. **Background and Rationale**

* significance of research question
* last sentence be the study purpose/main research question

1. **Study Objectives *(aims)*/Hypothesis**

* primary objective
* secondary objective(s)
* careful not to have too many

1. **Methods**
2. **Study design** (prospective, retrospective, randomized, cohort, etc.)
   * Include statement that IRB approval will be obtained
3. **Study population**
   * inclusion/exclusion criteria
4. **Study procedures**
   * Describe subject identification and/or recruitment
   * Describe informed consent process (written or verbal) *(prospective studies)*
   * Describe subject enrollment process *(prospective studies)*
   * Describe procedures for intervention, methods for blinding, randomizing, detailed description of what will occur once subject deemed eligible for study *(prospective studies)*
   * Describe criteria for assignment to study versus control group *(retrospective studies)*
   * Data collection, including all required data elements, sources, date ranges, and storage
5. **Outcome Measures**
   * primary outcome
   * secondary/tertiary outcomes
6. **Analytical Plan**

* Sample size calculation
* Methodology for measuring and evaluating each outcome

1. **Study Timeline**
2. **References**
3. **Appendices** (kept as separate documents)

- data collection tools, consent forms, patient information letters, surveys, etc.