**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.