**Protocol Outline**

Clinical question: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Background:**

* First paragraph: "the big picture," general context and problem being addressed
* Second/Third paragraphs: zero in on the topic of the research study
* Last paragraph: clarify the knowledge gap and the specific goal or question of the study
* Convince the reader why the study should be done

**Methods:**

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| **Protocol Section w/ Prompts** | **Details** |
| Research question- PICOT (Pop'n, Intervention, Comparison, Outcome, Time)- FINER (Feasible, Interesting, Novel, Ethical, Relevant) |  |
| Specific Aims- What are the "pieces" of info you need to answer your question?- Should involve your primary outcome(s)- Ballpark: 3-4 aims |  |
| Inclusion criteria - find middle between very homogeneous and very diverse- pts for whom benefits outweighs risksExclusion criteria- safety (e.g., allergic to tx)- unable to assess outcome- outcome unlikely to change- competing illnesses |  |
| Primary outcome(s)- should appear in your research question- define clearly- focus on how outcome will be measured- consider time element |  |
| Secondary outcomes- side benefits- potential harms- intermediate outcomes |  |
| Other key study data items- participant demographics- co-morbidities, disease severity- medications- health behaviors- tests, treatments administered- physician, site- adherence to treatment- can summarize & refer to detailed data collection sheet |  |
| Study design- Randomized clinical trial- Prospective cohort- Retrospective cohort- Diagnostic study- Cross-sectional- Survey |  |
| Study steps / data collection- source of participants- visualize what happens to patient during study (or care if retrospective) & describe- data sources- time points of data collection- blinding, randomization- length of follow-up- how data will be stored |  |
| Sample size / statistical analysis- State the difference in the primary outcome sought between study groups (or pre vs. post).- What statistical tests will be used for data analysis? |   |
| Ethical considerations- as applicable- consent, consent procedures- safety monitoring- information privacy/HIPAA- special/vulnerable populations |  |
| References- most should be peer-reviewed articles |  |