**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 risks  Exclusion 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 |  |