Format for a Research Project Protocol

Title:

Introduction and Background:

This should introduce the research area and provide the rationale for the significance of your project. The protocol should include a background of research performed within this area (with cites) and the significance of these. For example what is known, but what gaps are left.

If applicable include any preliminary studies, pilot work, or preparatory work you have carried out specific to the area of the proposal. Include summary data about your practice and or patient population that would lend to the significance of you carrying out this study in your patient population.

Close the last paragraph with this study's research goal.

Study Design and Methods:

1. Research hypothesis - Can be stated as hypothesis or research objective(s). What is primary objective and are there any secondary outcomes?
2. Study design - randomized controlled trial, observational cohort, etc. May include rationale or justification for selecting that design.
3. Describe the study population and add study inclusion and exclusion criteria. Where will study participants be recruited/selected? May want to include justification that the population described and your target number does exist in your clinic (feasibility).
4. Methods and Procedures for Data Collection.
    a. What will happen to the subjects - described by number of study visits and project procedures at each visit.
    b. What are the outcomes/data that you are collecting and at which visits. Some of these need to match the hypothesis/objectives and the outcome used for your sample size estimate.

Analysis:

Describe your data analysis process. What statistical test you will use to test each research objective that you listed? Perhaps you will only summarize the data and provide descriptive statistics. How did you arrive at your sample size estimate? Describe your sample size justification and your recruitment strategy to achieve this. Include the resources used to estimate the sample, such as anticipated effect size.
Consider consulting the SOM DBHI dept. for the Research and Statistical Consult Service, to assist in project design and data analysis - http://med.umkc.edu/dbhi/consultation/

Anticipated problems:

Discuss any anticipated problems you have considered and what contingency plans you have for those problems. For example:

Risks to subjects – how you monitor for problems and how they will be managed?
Recruitment – what if you don't enroll the # of subjects you need for power analysis?

Confidentiality:

Address how will you protect subject privacy and confidentiality with regard to study data security and other possible concerns related to your study procedures?