Protocol Title

Principal Investigator's name, address, phone number, email address

Some place the Sub-Investigators and their affiliations here
John/Jane Doe, M.D., Associate Professor
Department of Medicine
Wellstar Health System

Table of Contents:

1.0 Background

Background is the history of the disease, why it is important to study this particular disease/anomaly. Discuss how the disease affects the population, how many are affected, etc.

2.0 Rationale and Specific Aims

Rationale and Specific Aims is the "why" this study is important to conduct and what you plan to do.

3.0 Animal Studies and Previous Human Studies

Describe the process and outcome of the animal and/or laboratory studies that have been done. Also, if any previous human studies have been done (e.g., Phase I, other phases may be in a different population or for a different indication).

4.0 Inclusion/Exclusion Criteria

List the criteria:

- Bullet or number each criterion for easy identification.

5.0 Enrollment/Randomization

List the process for randomization and/or registration; list the address, phone number or website where the registration will take place.

6.0 Study Procedures

If multiple experiments are to be done, describe each separately. Include all interventions, experimental manipulations, data collection procedures, and measurements.

List the days and time frame of the study. Begin with Day 1, 0, or describe a washout period if applicable.

Example
Day 1: H&P, CBC, SMA7, ECG, etc.
Day 2: Administer study drug, etc.

Provide a description of what the participants will experience. For example, a description of the instructions that will be given to the participants, activities in which they will engage, the length and timing of involvement, and the circumstances under which they will provide data (e.g., phone calls, spending time in an uncomfortable position, group assessments, one-on-one interview, videotaping, audiotaping, etc.)

7.0 Risks

List all adverse effects observed in animal studies, previous human studies, or laboratory observations. List the frequency expected for the side effects and a statement that there may be unknown or unanticipated adverse effects.

8.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

List the process for AE reporting. Indicate where and how to submit AEs and the time frame in which to submit. List the regulatory authorities and their contact information for reporting.

9.0 Study Withdrawal/Discontinuation

List the process for withdrawing from the study. List the process for being withdrawn from the study and the indications for withdrawal.

10.0 Statistical Considerations

Describe the statistical power of the study, the confidence intervals and the method for analysis. Describe any possible deviations and their statistical impact.

11.0 Privacy/Confidentiality Issues

Discuss the methods for ensuring participant privacy and the methods for protecting privacy.

12.0 Follow-up and Record Retention

List the duration of the study. List the duration of record retention and the method for destruction or the possibility of indefinite archival of information.