A protocol is a written description of the research an investigator intends to conduct. The information provided in the IRB Application is a summary of the information provided in the protocol. It’s very important that the information provided in the IRB Application is consistent with the study protocol. Each of the following areas should be addressed in the protocol to describe what the investigator intends to do.

1. **Title of the Research Project**

2. **Background/Problem Statement:** Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of your study.

3. **Objectives:** List your research objectives, provide justification for the research, and the use of the results. You may reference grant application pages and attach as an appendix.

4. **Study Design/Methodology:** Describe the study design (e.g., single/double blind, retrospective chart review, etc) and the timetable for the study. Also Include:
   - Sample selection and size (number of subjects, age range, health status—Inclusion/Exclusion Criteria)
   - Describe the proposed intervention (if applicable)
   - Data collection procedures, instruments used, and methods for data quality control
   - Randomization information (if applicable)
   - Unit of analysis and observation

5. **Subject Recruitment Methods:** Describe plans for the identification and recruitment of subjects, including how the population will be identified, and how initial contact will be made with potential subjects by those having legitimate access to the subjects’ identity and the subjects’ information. Describe the setting in which an individual will be interacting with an investigator, when applicable.

6. **Informed Consent Process/Complete Waiver Process:** Describe the consent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent, who will seek consent when applicable.

7. **Research Procedures:** Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. Differentiate between procedures that will be performed specifically for this research project. Include a schedule of events, if applicable.

8. **Minimizing Risks:** Describe the procedures for protecting against or minimizing any potential risks, including risks of breach of confidentiality or invasion of privacy. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.

9. **Plan for Analysis of Results:**
   - Methods and models of data analysis according to types of variables
   - Programs to be used for data analysis

10. **Research Materials, Records, and Privacy:** Identify the sources of research material obtained from individually identifiable living human subjects. Indicate what information (records, data, etc.) will be recorded and whether use will be made of existing records or data. Explain why this information is needed to conduct the study. Specify how the data will be de-identified (if applicable), who has access to the data, where the data will be stored and how the researcher will protect both the data with respect to privacy and confidentiality. Address physical security measures (e.g., locked facility, limited access); data security (e.g., password-protection, data encryption); safeguards to protect identifiable research information (e.g., coding or links)

11. **References**

**NOTE:** Please add a version date to your protocol.