Protocol Requirements

The research protocol should include descriptions that are detailed enough for the reviewers to understand what is being done. The following sections should be included in the research protocol:

1. Specific Aims
   List the broad, long-term objectives and describe concisely and realistically what the research is intended to accomplish and the hypotheses to be tested.

2. Background and Significance
   Give a brief background that critically evaluates the current knowledge and identifies gaps in the knowledge that the proposed research is intending to address. Cite literature and include a reference list.

3. Research Design and Methods
   Describe the research design and procedures to be used to accomplish the specific aims of the project. Include the means by which the data will be collected, analyzed, and interpreted. When describing the design and methods, be sure to include: 1) New methodology used and its advantages over older methodology; 2) Potential limitations of the procedures and possible alternative approaches; 3) Tentative sequence or time table of events; and 4) Specific procedures, situations, or materials that may be hazardous to personnel and precautions to ensure their safety.

   Provide a description of the population sampling procedure. Justify the sampling procedure proposed as well as the sample size. Complete a statistical plan for analyzing the collected data.

   Identify all drugs and/or devices to be used, if applicable. Note the proposed dosage information including instructions for administering, adverse effects, compatibility, and stability. Provide handling instructions as well as storage and disposal procedures.

   Identify and clearly explain all procedures and/or interventions that will be performed in this protocol. When collecting biological samples, clearly explain how the samples will be collected as well as storage, testing, and disposal methods. For behavioral research, be sure to identify the instruments being used and who will be administering the instruments.

4. Study Population

Describe the characteristics of the study population. Include the anticipated number of normal volunteers, age ranges, gender, ethnic background, and health status. Identify all inclusion/exclusion criteria and justify each criteria. Explain the use of special classes of subjects, including vulnerable and potentially vulnerable subjects; especially those in which ability to obtained informed consent may be questionable.

5. Human Subjects (Risk and Benefits)
   Identify the sources of research material obtained from the study subjects in the form of specimens, records, or data. Indicate whether or not the materials will be obtained prospectively, or if the materials will come from previously existing specimens, records, or data. Explain what information will be used to identify potential human subjects for inclusion in research.

   Describe the plan for recruitment of subjects as well as the informed consent process, including the circumstances under which consent will be obtained, who will be obtaining consent, and how consent will be documented. Be very clear about the consent process for vulnerable and potentially vulnerable populations. If requesting a waiver of consent, indicate why it is necessary.

6. Risks and Side Effects
   Describe any potential risks, including medical, psychological, legal, financial, and/or social risks; and assess their likelihood and/or seriousness. Describe any alternative treatments or procedures that may be advantageous to the participants.

   Describe the procedures for protecting against or minimizing the risks described above, including risks to confidentiality, and assess their likely effectiveness. Discuss provisions for medical and professional intervention in the case of an adverse event. Describe any provisions for monitoring the data for safety.

   Discuss why the risks are reasonable in relation to the benefits to the subject as well as in relation to the importance of the knowledge being gained.

7. Benefits
   Explain the expected benefits in relation to the subjects. If there are none, then state this. Explain the benefit to general science or others if applicable.

8. Costs/Compensation to Subjects
   Clearly describe the financial costs that the subject may incur. This should include any provisions for payment of travel, interventions, tests, labs, or medical care due to the research.

Describe any compensation that is received by the subjects, whether monetary or otherwise. When determining compensation, keep in mind what is reasonable based on the time and effort required of the subject. The use of benefits to offset the burden due to participation in the research should be incremental and not based on study completion.

9. Confidentiality

   Describe appropriate provisions to protect the privacy of the subjects and maintain the confidentiality of the data; including safeguards to protect the rights and welfare of vulnerable populations. Information regarding who will have access to the data is required. Provide a plan for record retention and disposal once the study is complete.

   Provide a clear description of how the data will be disseminated. Outline the sharing of data with others outside of the institution, and include provisions for maintaining confidentiality. Additionally, describe how the results of the data will be used (i.e. presentations at professional organizations, submission to professional journals).