Protocol Summary:

Principal Investigators are required to prepare a summary of the protocol to include the following:

I. Full title of the protocol, Investigators

II. Introduction/Literature Review- summarize relevant literature that led you to research problem and approach.

III. Objectives: research question, purpose of the study, hypothesis

IV. Study type: Retrospective or Prospective

V. Methods: location, start and stop dates, type of research (Biomedical, Drug, Biologic, Device, Tissue/Blood specimen, other), inclusion and exclusion criteria (should be justified in the background information/literature review), subject recruitment and screening (number of subjects, age, gender, English speaking, subject materials, promotional advertising (promotional advertisements used for recruiting subjects must be submitted to the ARMC-IRB for review and approval), etc.

   a. Consent Process: Specific description of informed consent process to include—but not limited to: who, how, training, when, where, considerations, privacy and time for decision-making/discussion, consent capacity determination (who and how); Method of subject identification and randomization: coding system, subject randomization/group selection process; Privacy of Medical and Research Records information/medical records, Medical Release forms, HIPAA compliance/authorization form

      'Identifiers of our single patient are strictly limited to medical record number, ethnicity, age and sex, along with associated clinical data. All published poster presentations, abstracts and papers will be de-identified, with all names, medical record numbers and any other identifying material removed. Patient's age, sex and race will be used in publication for educational purposes. Only the principal investigator, co-investigator and research coordinator will have access to the data that is obtained. Medical records and presentation documents will be kept within an encrypted password protected file on a password protected computer that is accessible only to the investigators involved in the study'

VI. Study Design and Analysis: Description of interventional procedures and data collection procedures: to include lab evals, tests, specimen amounts and schedules, clinical assessments/schedule/follow up procedures, case report forms, data collection forms (with description of subject codes), study instruments, rating scales, interview guides, plans for statistical analysis of data when appropriate. Please include any additional information that will assist the ARMC-IRB in the review of your protocol.

   a. If an Investigational New Drug (IND) is involved, provide the following information: (1) name of drug, (2) source of drug, (3) dosage and schedule of administration, (4) status with Food and Drug Administration and IND#, (5) review of animal studies and previous human studies, (6) reported side effects.

   b. For an approved drug used in an experiment, provide similar information: (1) name, (2) source, (3) dosage, (4) how administered, (5) side effects.

   c. If an Investigational Device (ID) is involved, provide the following information: (1) name of device, (2) manufacturer, (3) status with Food and Drug Administration and ID#, (4) review of animal studies and previous human studies, (5) reported adverse effects.

VII. Risks/Benefits: assess potential risks to subjects, benefits either direct or indirect by adding to body of knowledge.

   a. Less than minimal risk: research in which there is no known physical, emotional, psychological, or economical risk. This research qualifies as exempt if it does not involve special populations (i.e., minors, prisoners, pregnant women, etc.).

b. Minimal risk: means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
c. Greater than minimal risk: research procedures that may include risk beyond that ordinarily encountered by subjects (e.g. maximal exercise testing, experimental drugs, biologics or medical devices, stressful psychological testing, use of special populations). This research requires some benefit analysis comparable to the risk and full review by the IRB.

VIII. Funding Source: Any funding source should be indicated in the protocol and the application. Note if subjects will be compensated, if so, how much.

IX. References in the following format:
a. Doe, John. *Article Title*. Journal of Medicine. Date etc.