Research Study Name
PI Name, Sub-I Name
Protocol

A complete description of the planned research (i.e., protocol) must be submitted with initial applications for IRB or exempt review. The research protocol should provide the information needed for reviewers to determine that the regulatory and Human Research Protection Program (HRPP) policy requirements have been met. There is no required format or template; different sections and formatting may be used, provided the necessary information is included.
For additional information on submission for IRB or exempt review, see HRPP policies, *IRB Submission and Pre-Review* and *Exempt Research*.

I. Objectives
The purpose of the study (research questions and / or study objectives) should be clearly and succinctly stated. In experimental designs, objectives will be stated as hypotheses to be tested.

II. Background and Rationale
Summarize and synthesize the available research (including published data with citations) to provide justification for the study. Evaluate prior research for relevance to the research question under study. When the proposed research is the first of its type to involve human participants, the results of relevant animal studies must be included. Discuss the anticipated results and potential pitfalls. Describe the significance of the research including potential benefit for individual subjects or society at large. Discuss how public health and social welfare might be enhanced.

III. Procedures
The procedures should include the following:

A. Research Design
The research design should be identified and should be appropriate to answer the research question(s) under study. Describe the type of research proposed (e.g. experimental, correlational, survey, qualitative) and specific study design that will be used (e.g. pre-test /post / test control group design, cross-sectional design; prospective longitudinal cohort design; phase III double-blind randomized control group design).

B. Sample
Describe the sampling approach. For experimental designs, include justification for sample size determination. Identify the procedures that will be used to recruit, screen, and follow study volunteers. Specifically define the study sample (number of subjects to be enrolled, characteristics of subjects to be included in and excluded from the research).

C. Measurement / Instrumentation
Identify the variables of interest and study endpoints (where applicable). Justify measurement techniques selected. Provide validity and reliability data for selected measures.

D. Detailed study procedures
Methods for study data collection and for avoiding / minimizing subject risks should be included. Include a timeline for subject evaluations and the duration of subject participation in the project. Also include the expected timeframe from beginning to end of the study. Identify the plans the proposed safeguards for subject confidentiality (plans for coding data and for securing written and electronic subject records). Indicate how long personal information will be stored once the

study is completed. Methods will vary with the research approach used (qualitative, quantitative). The selected methods should be sufficiently described to justify the use of the approach for answering the defined research question. Methods should also be described in adequate detail so that IRB members may assess the potential study risks and benefits.

E. Internal Validity
Threats to internal / external validity should be considered. Describe measures that have been taken to avoid study bias.

F. Data Analysis
Specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g. specific descriptive or inferential tests) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analytic approaches.

IV. Bibliography
Include a reference list of literature cited to support the protocol statement.

Notes:

Please understand that any time a protocol needs to be revised, you must submit a Request for Amendment to the IRB outlining the protocol changes, along with a copy of the revised protocol.