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# Newton-Wellesley Hospital
# Writing a Research Protocol Guidelines

Once an investigator has reviewed and established a valid research question, the study design and plan must be developed. The written plan of the study is called the "Protocol". Writing a protocol helps the Investigator organize the research in a logical, focused, efficient manner. Please contact the Office of Research if you have any questions.

The following is a basic outline to assist in protocol preparation. Every research study is unique and must be approached on an individual basis. Accordingly, additional information beyond the guidance below may be required.

1. **INTRODUCTION**: Explain the background and rationale for why the research question is important. Provide information that will support the research proposal and explain the development of the research question. Explain the results of any past studies, animal studies, clinical and experimental findings, and other supporting data that have led to the research project.

2. **STUDY OBJECTIVES**: The study objectives describe the purpose of the study. Clearly state the research questions/hypothesis to be tested. The objectives are usually described briefly in one or two sentences that are presented in a logical sequence.

3. **STUDY DESIGN**: The study design usually includes:

    a. **The Type of study** – Explains the approach the investigator plans on using to obtain a satisfactory answer to the research question
    b. **The Location of the study** – Explains the specifics of where the study will be carried out as well as where the subjects will be located while receiving treatment on the protocol
    c. **The Duration of the study** – Estimates the duration of time for the entire study

4. **SUBJECT SELECTION**: Define the study population and the requirements for enrollment in the study. Clearly establish the inclusion/exclusion criteria to ensure that the subjects who are enrolled in the study meet the target population to correctly answer the research question.

5. **RESEARCH PLAN**: An orderly description of all of the intended procedures that directly affect the subjects. This plan should establish a step-by-step detailed description of the subject treatment plan, including any follow up visits. This plan should also address the screening, safety and efficacy assessments, study medication/device intervention, lab evaluations, economic considerations, adverse events and reporting, follow-up, removal of patients from the study, and the study completion.

6. **DATA COLLECTION & STATISTICAL ANALYSIS**: The investigator must develop plans for managing, and analyzing study data. There should be processes for maintaining subject confidentiality, monitoring schedule, storage and retention of research files, and the steps for performing statistical analysis.

7. **APPENDIX**: Any attachments that are referenced in the protocol should follow the main body of the protocol. Often, the appendices are schemas (timetable of study visits/procedures), staging criteria for disease and toxicity, questionnaires, applicable policies related to the research study, data collection guidelines, or any other specific that will assist in the conduction of the research protocol.

8. **REFERENCES**: List all publications that were referenced to in the writing of the research protocol.