

# ELEMENTS OF A RESEARCH PROTOCOL

## **Introduction and Background**

A review of what is known and not known about the issue, why it is important and how this study will fit into the larger picture of knowledge on the subject. This section should review the relevant literature and should be written so that persons not familiar with the scientific field can understand it.

## **Source of Funding**

Who is funding your project? Some sources may require a Single Project Assurance (SPA) **after** the project is approved by an IRB. If a SPA is required, be prepared to inform the IRB so the appropriate paperwork can be processed.

## **Other IRB Reviews Conducted**

If your project has been reviewed by another IRB, a copy of their written approval or recommendations should be attached to the proposal being presented to the UDOH IRB.

## **Research Questions/Objectives**

The question(s) that the study will attempt to answer. The objectives should be stated as clearly as possible and should allow the reviewer to determine whether the chosen study design is appropriate.

## **Study Design**

This section should state the hypothesis to be tested and describe the study design including, whether it is experimental or not, use of a control or comparison group, randomization or other allocation methods, and interventions to be performed. The reviewer should be able to determine that the design to be used is appropriate to answer the research question(s).

## **Methods to be used in obtaining consent (Informed Consent Form Should Accompany Proposal)**

The Informed Consent Form should be written in simplified language that can be understood by the subject or persons you are seeking consent.

## **Subjects**

This section should describe the target population of the study and how subjects will be recruited and selected for entry into the study, including recruitment or selection methods, and inclusion and exclusion criteria. The target enrollment or sample size should be stated. If human subjects will be involved, explain how you will comply with HHS requirements for the Protection of Human Subjects (Title 45, Code of Federal Regulations, Part 46).

## **Study Procedures**

This section should describe what will happen in the study. Depending on the study it might include number of visits, measurements that will be made, (e.g., questionnaires, physical measurements, measurements on biological samples), and investigational treatments or other interventions. Schematic diagrams or flow charts may be useful for this section. For intervention studies, outcomes should be stated as well as methods for dealing with adverse reactions of the intervention.

## **Data Management & Analysis**

This section should describe the anticipated analytic and statistical methods to be used. The factors determining, approach to estimating, and justification for choice of sample size should be described. The methods should complement the study design and address the research question(s).

## **Confidentiality**

Explain how records and individually identifiable health information will be protected. Describe any legal protection that apply to your data.

## **Implementation Plan/Timetable**

This section should describe how and by whom the different steps of the study (e.g., pretesting of questionnaire, enrollment of subjects, interviews, data entry, data management, data analysis) will be carried out, and the facilities to be used. A time-line is very useful to assist in determining the feasibility of the study plan.

## **References and Appendices**

This section should include pertinent references reviewed and may include key articles, results of prior research by the authors and anything else deemed appropriate to assist in the review.

## **Suggested references to assist in developing a research protocol**

Hulley SB, Cummings SR (eds). *Designing Clinical Research*. Baltimore: Williams & Wilkins. 1988. Polit DF, Hungler BP. *Nursing Research. Principles and Methods*. 4th edition. Philadelphia: J.B. Lippincott Co. 1991.