

# How to Create a Research Protocol

The Research Protocol is a statement of the researcher's project design and a description of his/her responsibilities toward the human subjects involved in the research.

To ensure an effective review by the Institutional Review Board, a full description of the planned research must be submitted with the Application for IRB Review. A research protocol provides the reader with background information of the problem under study, including the study rationale, a detailed plan for conducting the research involving human research participants, and a discussion of the potential importance of the research.

## **1. Objectives**

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

## **2. Background and Rationale**

Summarize and synthesize the available research (including published data) to provide justification for the study. Evaluate prior research for relevance to the research question under study. Describe the significance of the research including potential benefits for individual subjects or society at large.

## **3. 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.

### **b) Sample**

Describe the sampling approach to be used. 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, and whether this will be a random or convenience sample).

### **c) Measurement/Instrumentation**

Identify the variables of interest and study endpoints (where applicable). Justify measurement techniques selected. Provide information regarding the validity and reliability of selected measures.

#### **d) Detailed study procedures**

Methods for collecting data and for avoiding / minimizing subject risks should be included. Include a timeline for subject participation in the project. Identify how subject confidentiality will be safeguarded (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.

### **4. Bibliography**

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