

# Research Protocol Template

Title of the study:

IRB # (If known):

Principal investigator:

Co-investigator(s):

Additional Personnel:

Statistician:

Protocol Version or Date:

**NOTE: Be sure to delete all text in italics before submitting the protocol for review.**

## Abstract

**DESCRIPTION:** *State the application's broad, long-term objectives and specific aims, making reference to the clinical relevance of the project. Concisely describe the research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of first person. This description is meant to serve as a succinct and accurate description of the proposed work when separated from the application.*

## Research Plan

The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document. Be specific and informative, and avoid redundancies.

### I. Specific Aims

*"What do you intend to do?" Introduce this section by declaring the broad, long-term objectives of your research efforts. List the specific research aims of this particular research proposal. State the hypotheses to be tested. No more than one page is recommended.*

*The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document. Be specific and informative, and avoid redundancies.*

### II. Background and Significance

*"Why is the work important?" In this section, briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and clinical relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. No more than one page is recommended.*

### III. Progress Report and Preliminary Studies

*"What has already been done?" In this section, provide an account of the principal investigator's preliminary studies pertinent to the application or any other information that will help to establish the experience and competence of the investigator to pursue the proposed project. Approximately one page is suggested for this section.*

### IV. Research Design and Methods

*"How are you going to do the work?" In this section, describe the research design and the procedures to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Include a description of statistical analysis. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and how you overcame them. Discuss alternative approaches to achieve the aims and discuss why you did not choose them. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.*

The research design and methods section should follow a standard format and be as concise as possible. A recommended format for this section including subsections follows:

- a. **Study Design or Overview:** Describe the study design and rationale for choosing the study design.
- b. **Study Subjects:** Describe how study subjects will be selected. List eligibility and exclusion criteria.
- c. **Sample Size:** Explain how many subjects will be studied and whether sufficient subjects will be available based on statistical tests of hypotheses.
- d. **Data Collection:** Describe the data to be collected and any laboratory techniques that will be used.;
- e. **Data Handling:** Explain how data will be prepared for analysis. Will data be entered into a computer for analysis? Explain steps taken to assure accurate and complete data collection. Describe data storage and archiving.
- f. **Data Analysis:** Explain details of data analysis, descriptive statistics, tests of hypothesis, and expected formats for presenting results.
- g. **Feasibility and Time Frame:** Describe a realistic time frame for completing the work. Include evidence that the subjects planned for inclusion in this study exist and can be recruited, entered, and maintained throughout the study in the timeframe proposed.
- h. **Strengths:** Describe the strengths of the proposal design and methods.
- i. **Limitation:** Describe problems that may arise and plans to resolve any potential difficulties.

## **V. Human Subjects**

- a. **Detailed Description:** Provide a detailed description of the proposed involvement of human subjects in the work previously outlined in the Research Design and Methods section.
- b. **Population:** Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable.
- c. **Research Materials:** Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.
- d. **Recruitment of Subjects:** Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.
- e. **Potential Risks:** Describe potential risks (physical, psychological, social, legal, or otherwise) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.
- f. **Protection:** Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.
- g. **Benefits:** Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If a test article (investigational new drug, device, or biologic) is involved, name the test article. State whether the 30-day interval between submission of applicant certification to the Food and Drug Administration and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration.

## **VI. Gender/Minority Mix**

All protocols must include minority subjects and both genders unless exclusion is scientifically justified. An exception can also be made when a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

*The study population should mirror the national demographics unless the protocol is designed specifically to fill in a gap of knowledge. If a minority group is excluded or inadequately represented, appropriate outreach measures to recruit the underrepresented group(s) must be described. If a gender is excluded, the reason for exclusion must be given.*

**VII. References:**

*List references cited.*

**VIII. Other:**

*a. **Budget:** Prepare as applicable. The budget should address each aspect of the proposed study. Include justification for each major area of expenditure. This should include details and a justification for how much time that the investigator plans to spend on each aspect of the study.*

*b. **Progress Report:** Keep in mind that at the conclusion of Year 1, it may be necessary to submit a progress report that clearly and unambiguously addresses the following issues:*

*-Describes the progress that has been made toward achieving the stated aims of the proposal, including all publications and presentations resulting from this work.*

*-Describes the preliminary data and its significance.*

*-Provides a clear timeline for the completion of each major task necessary to complete the study.*

*-Describes plans for obtaining support for future research projects.*