**RESEARCH GRANTS PROGRAM**

# GUIDE FOR WRITING A RESEARCH PROTOCOL

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## PAN AMERICAN HEALTH ORGANIZATION

## *GUIDE FOR WRITING A RESEARCH PROPOSAL (PROTOCOL)*

**The protocol may not exceed 20 single-spaced, letter-size pages containing approximately 62 characters per line.**

Proposed studies that involve the use of questionnaires or guides for data collection ***should have an annex containing copies of the instruments and should indicate their stage of preparation*** (e.g., version for pilot testing, final version, etc.).

To facilitate the investigator's task, a basic outline for writing the proposal and a brief description of each component, are provided below. **These are guidelines, which should not necessarily be applied rigidly. How they are applied will depend on the type of study and the methodological approach of each investigator.**

### BASIC OUTLINE OF A RESEARCH PROTOCOL

**TITLE OF THE RESEARCH PROJECT**

**PROJECT SUMMARY**

**STATEMENT OF THE PROBLEM** (scientific justification)

**JUSTIFICATION AND USE OF THE RESULTS** (final objectives, applicability)

**THEORETICAL FRAMEWORK** (argumentation, possible answers, hypothesis)

**RESEARCH OBJECTIVES** (general and specific)

**METHODOLOGY**
- Operational Definitions (operationalization)
- Type of Study and General Design
- Universe of Study, Sample Selection and Size, Unit of Analysis and Observation, Selection Criteria
- Proposed Intervention (if applicable)
- Data Collection Procedures, Instruments Used, and Methods for Data Quality Control
- Procedures to Ensure Ethical Considerations in Research with Human Subjects

**PLAN FOR ANALYSIS OF RESULTS**
- Methods and Models of Data Analysis according to Types of Variables
- Programs to be Used for Data Analysis

**BIBLIOGRAPHIC REFERENCES**

**TIMETABLE**

**BUDGET**

**ANNEXES** (Data collection instruments, elaboration on methods and procedures to be used, etc.)

## GENERAL ORIENTATION FOR COMPONENTS OF THE OUTLINE

Outlines may vary according to the preference of each investigator. However, the scientific community has agreed that all proposals should at least contain: The problem statement and justification for the research, the general and specific objectives, the chapter on methodology, the plan of analysis, and the timetable and budget.

As a general guide, an orientation is provided on what the investigators are expected to develop for each component of the protocol.

## TITLE OF THE RESEARCH PROJECT

A good title should be short, accurate, and concise. It should make the central objectives and variables of the study clear to the reader (reviewer). The title provides the "key words" for the classification and indexing of the project. If it is possible without undue length, the title can give a preview of the protocol. It is important to specify what population or universe will be investigated. For example: Effects of the program for rooming-in at home on breast-feeding indicators: Experimental test with low-risk primiparous women attended at La Esperanza Maternal Hospital in Guatemala City.

## PROJECT SUMMARY

The abstract should give a clear idea to the reader of the central question that the research is intended to answer and its justification. It should specify the hypotheses (if applicable) and the research objectives. In addition, the abstract should briefly describe the methods and procedures laid out in the chapter on methodology.

## STATEMENT OF THE PROBLEM

This constitutes the scientific justification for the study; i.e., the basis of the need for research to generate further knowledge that will contribute to existing knowledge. The statement must be written in a way that gives empirical references to describe the situation and also clearly specifies the gaps in existing knowledge of the problem and/or the existing controversy and the nonconclusive evidence. Moreover, there may be very conclusive evidence for knowledge considered to be established, but the investigator questions the accumulated knowledge because of certain events that he or she intends to subject to verification. It is at this point where the investigator defines the object of study **and conveys the questions or broader issues motivating the research**. A logical sequence for presenting the statement would be

- Magnitude, frequency, and distribution. Affected geographical areas and population groups affected by the problem. Ethnic and gender considerations.

- Probable causes of the problem: What is the current knowledge of the problem and its causes? Is there consensus? Is there controversy? Is there conclusive evidence?

- Possible solutions: In what ways have solutions to the problem been attempted? What has been proposed? What are the results?

- Unanswered questions: What remains to be answered? What areas have not been possible to understand, determine, verify, or test?

The problem statement should make a ***convincing argument*** that there is not sufficient knowledge available to explain the problem and its possible alternative solutions, or it should make a ***convincing argument*** for the need to test what is known and taken as fact, if it is called into question by new findings or conditions.

The discussion in this section should show that the investigator has documented this problem and performed an exhaustive bibliographic review of the subject.

## JUSTIFICATION AND USE OF THE RESULTS

This section describes the type of knowledge expected to be obtained and the intended purpose of its application. It should indicate the strategy for disseminating and using the research findings according to the potential users of the knowledge generated. The justification should answer the following:

- How does the research relate to the priorities of the Region and the country?
- What knowledge and information will be obtained?
- What is the ultimate purpose that the knowledge obtained from the study will serve?
- How will the results be disseminated?
- How will the results be used, and who will be the beneficiaries?

The justification, which can be included as part of the statement of the problem or in a separate section, should make a ***convincing argument*** that the knowledge generated will be useful and generally applicable within the regional context.

## THEORETICAL FRAMEWORK (Background)

This is derived from the statement of the problem (presentation of empirical evidence and central question) and is the argumentation and demonstration that the "question" has a basis (grounds) for probable answer(s) and/or working hypotheses.

- Establishment of relationships (identification of the relationships between the independent variable and the response variables). What is known, and how has it been explained? Are the results conclusive? What are the bases of the question?
- How are the possible answers to the question explained and defended? What are the assumptions? What are the relationships? What are the working hypotheses?

The theoretical framework, considered the "grounds" that support the central question of the study, states the investigator's reasoning and arguments for the attempt to find the evidence that will offer an answer to the question and/or hypothesis. It also requires an exhaustive bibliographic review.

## RESEARCH OBJECTIVES (General and Specific)

These should be defined after the theoretical framework has been developed, and the sequence is clear between the central question and possible responses to the questions and/or working hypotheses. This is recommended because the definition of the objectives is simply the operationalization of the answers and/or hypothesis formulated by the investigator.* They are the intellectual activities that the investigator will perform throughout the research process.

- **General Objective**: This should specify what kind of knowledge the study is expected to obtain. It should give a clear notion of what is to be described, determined, identified, compared, and, in the cases of studies with working hypotheses, confirmed.

  *Example*
  - To verify the differences in the length of time low-risk primiparous women breast-feed when they participate in the program for rooming-in at home as compared to those who do not participate.

- **Specific Objectives**: These disaggregate and follow logically from the general objective. They are a preliminary view of the research design.

  *Examples*
  - To estimate the prevalence of breast-feeding in low-risk primiparous women covered by the program for rooming-in at home and the prevalence of breast-feeding in primiparous women that receive standard health care.

  - To determine the existence of statistically significant differences in the prevalence of breast-feeding in the group of women who receive standard health care and the group treated at home.

  - To identify the protective factors that from the women's perspective help to explain the differences in the prevalence of breast-feeding according to the type of attention received.

## METHODOLOGY

The methodology explains the procedures that will be used to achieve the objectives. In this section the operational definition for the variables used should be specified in detail, along with the type of variables and the ways to measure them. In addition, the methodology should consider the study design and the techniques and procedures used to achieve the proposed objectives. A description is given below of what the investigator is expected to specify in the methodology:

### Operational Definition of Variables

Based on the concepts that may be made explicit in the theoretical framework, the variables should be made operative; i.e. the investigator should clearly describe what is understood by each variable, what type of variable is being considered, and the way its values are to be

*It is recognized that not all research requires the formulation of a hypothesis for subsequent empirical verification. However, all research should explain its general and specific objectives.

reported (quantitatively, when the variable is numerical and qualitatively, when the variables do not have numerical values).

Operationalization is a process that will vary in accordance with the type of research and research design. However, the variables should be clearly defined and appropriately operationalized.

**If by the time the protocol is prepared this stage has not been reached, it will be necessary to explain in detail the procedure by which the definitions are expected to be generated or, if appropriate, to justify why variables are not to be used in the research.**

Protocols will be considered incomplete if their operational aspects are vaguely formulated; for example, "The pertinent and relevant variables will be studied," "demographic and social variables will be considered," or when the statement is so imprecise that it does not allow the relevance of the variables and their use to be appraised.

**Type of Study and General Design**

The type of study and its design should be decided on the basis of its proposed objectives and the availability of resources, in addition to ethical considerations. The investigator should clearly state the type of study that will be conducted and provide a detailed explanation of its design. On this point, the investigator should also state the strategies and mechanisms that will be used to reduce or eliminate threats to the validity of the results, i.e. the so-called confounding factors (in the selection and assignment of subjects, the loss of cases, and the control of instruments and observers, etc.). These factors can be elaborated on when they are taken up in greater depth in their respective sections.

*Example*: An experimental controlled study will be conducted with two groups of women; those who participate in the program for rooming-in at home, and those who only receive standard care. Selection will be made of low-risk primiparous women who have been seen in the maternal and child hospital, have received at least two prenatal controls, and reside in the area of influence of the hospital. There will be two groups formed, which will be randomly assigned.

**Universe of Study, Sample Selection and Size, Unit of Analysis and Observation, Selection Criteria**

In this section the investigator should describe the universe of study and all aspects of the selection procedures and techniques and the sample size (if this is not applicable, an explanation should be given). For both probability samples and non-probability samples (samples of convenience or grab samples) the investigator should indicate the procedure and criteria used and justify the selection and size.

In the case of studies using non-probability samples, in which subjects are selected for focus groups or as key informants, etc., the investigator should specify the selection criteria, the type of group and its size, and the procedures used to establish the group.

Here too, it is necessary to mention the selection criteria for the subjects or units of observation and the procedures to control factors relating to sample selection and size that can affect the validity of the results.

**Proposed Intervention** (if applicable)

This section should be prepared when the research objectives and design provide for an evaluation of the results of an intervention (educational program, vaccine, treatment, etc.). Generally, these are comparative studies with experimental or quasi-experimental designs, before and after, where assessment is made of results attributable to the intervention. There should be a full description provided of the intervention and an explanation given of the activities in their order of occurrence. It is essential that the description of the intervention answer three fundamental questions: Who will be responsible for the intervention? Where will it take place? What activities will be performed, and with what frequency and intensity?

Many research efforts that include interventions involving human subjects require an ethical review. In these cases, the investigator will be required to include a section in reference to this area.

**Data Collection Procedures, Instruments Used, and Methods for Data Quality Control**

The investigator should write up the procedures that will be used (population survey, in-depth interviews, non-participant observation, focus group dynamics, content analysis, etc.), how and when the procedures will be used, and the instruments that will be used to collect information (questionnaire, interview guide, observation recording form, guide for a focus group moderator, content analysis guide, etc.). Procedures or techniques that are standardized and/or documented in the literature should be described briefly, and bibliographic references should be given to sources where the details of these procedures and techniques can be found.

This section must describe in detail the procedures to be used to control the factors that undermine the validity or reliability of the results (controls for observers or persons responsible for compiling the information, and controls for the instruments).

If the use of secondary data is required, the investigator will describe their sources, content, and quality so that it will be clear that the information required for the study is available. If use is made of historical, journalistic, or other similar types of documentary sources, indication should be provided of the sources and techniques that will be used to collect and analyze the information.

***The protocol should have an annex containing the instruments that will be used (questionnaires, interview guides, moderator guides, registration forms, etc.),*** and it should indicate their stage of preparation.

**Procedures to Ensure Ethical Considerations in Research with Human Subjects**

When the research involves human subjects, this section should explicitly provide for the following aspects:

- The known benefits and risks or disadvantages for the subjects in the study.

- Exact description of the information to be delivered to the subjects of the study and when it will be communicated orally or in writing. Examples of this information include: the objectives and purposes of the study, any experimental procedures, any known short- or long-term risks, possible discomforts, expected benefits of the procedures used, duration of the studies, alternative methods for treatment if the study is a clinical trial, suspension of the study if a finding is made of negative effects or if there is sufficient evidence of positive effects that do not justify continuing with the study, and the freedom of subjects to withdraw from the study whenever they want.

- When appropriate, indicate any special incentive or treatment that subjects will receive through their participation in the study. If there is any type of remuneration, specify the amount, method of delivery, time, and reason why payment is required.

- Indicate how the information obtained from participants in the study will be kept confidential.

- List the drugs, vaccines, diagnoses, procedures, or instruments to be used, whether they are registered, unregistered, new, or currently in use in the country.

Moreover, responses are required for other ethical aspects, such as:

- In studies where personal information will be obtained from the subjects, indicate how the information will be kept confidential.

- For studies involving the participation of subjects in an experiment (experimental or quasi-experimental trials, studies of interventions, etc.), information should be provided on the free and informed consent of the participants and the strategy that will be used to obtain it.

- Brief synopsis of how the research findings will be reported and delivered to the subjects involved in the study or to other interested parties.

- Indicate and justify the inclusion, as appropriate, of children, the elderly, physical challenged, and pregnant women. Justify the non-inclusion in the study group, if appropriate, of women (of any age), an ethnic minority, racial group, etc.

- When appropriate, indicate how the appropriate balance of the two sexes will be ensured in the study groups. In addition, indicate, when appropriate, how gender inequities and discrimination and disadvantages can affect women's involvement in the research.

When studies involve human subjects, an institutional ethics committee in the country where the research will be conducted should evaluate and endorse the research, preferably before it is submitted to the Research Grants Program. For this purpose, the form for research involving human subjects should be filled out, and care should be taken to attach the informed consent form that will be signed by the subjects involved in the study. If the Internal Advisory Committee on Research recommends it, the project will be reviewed by the PAHO Ethical Review Committee prior to its final approval by the Director, and the RGP will request additional information if necessary.

## PLAN FOR ANALYSIS OF RESULTS

Although this item is considered under the methodology, it is suggested that the investigator treat it as a separate section. Indications are given below of what is expected from a plan of analysis.

### Methods and Models of Data Analysis according to Types of Variables

In accordance with the proposed objectives and based on the types of variables, the investigator should specify how the variables will be measured and how they will be presented (quantitative and/or qualitative), indicating the analytical models and techniques (statistical, non-statistical, or analytical techniques for non-numeric data, etc.). The investigator should provide a preliminary scheme for tabulating the data (especially for variables that are presented numerically). It is recommended that special attention be given to the key variables that will be used in the statistical models.

### Programs to Be Used for Data Analysis

Briefly describe the software packages that will be used and their anticipated applications.