

Development of a Minigrant Proposal for a NON-RESEARCH Project Description of Commonly Used Components

Introduction

Studies are conducted in response to problems, such as an epidemic or an unexpected health outcome, or in response to a need to plan or change a program or course of action, to test a hypothesis, or to further study recent findings. Scientific or medical curiosity also stimulate studies.

You need to develop a plan or protocol as a guide for the study. The format and content of mini proposals vary widely. These materials will describe the standard information usually included in a proposal.

1. Proposal Abstract

The abstract is a summary of your proposed study. It is not written until all other sections of the proposal are completed, though it is usually presented as the first section of the proposal. The abstract should be brief – usually about 200 words – and should answer as many of the following questions as possible:

- What is the problem to be studied?
- What are the research questions or hypotheses?
- What are the expected implications of the study?
- Who will conduct the study (data collection and/or analysis)?
- When will the study be conducted (data collection and/or analysis)?
- Where will the data collection be conducted?
- What methods will be used to collect and/or analyze the data?
- What resources are required to conduct the study?

2. Problem Identification and Definition

This section of the proposal depends on information from previous research and the literature. Therefore, it should contain the literature review. Before writing this section, you should:

- * Search the literature for information about the problem you are researching.
Determine whether others are currently engaged in similar or related research.

- * Classify key literature on the subject.
- * Identify critical areas for research (e.g., shortcomings of previous studies or areas where no research has been done).

Identify the problem. State why you think the problem requires study.

1. Indicate the discrepancy between the real or observed situation (what is) and the ideal, desired, or theoretical situation (what should be).
2. Indicate the alternative solutions or explanations for the discrepancy.
3. Indicate which of the alternatives you believe is the most likely to be correct and why.

Note: For exploratory or descriptive research, only the first condition is required. Conditions 2 and 3 may or may not apply.

Define the problem. Summarize current research and list issues needing further study.

The *Problem Definition* may include information on:

- * Magnitude. What is the incidence and prevalence of the problem?
- * Time frame. When does it occur? Is it current?
- * Geographic area. Where does the problem generally occur?
- * Population. Does the problem affect certain groups of people? If so, what are their characteristics?
- * Why? What are the probable reasons for the problem? Is there agreement or conflict over these reasons?
- * Solutions. What solutions have already been tried? How successful have they been? What untried solutions might be possible?
- * Unanswered questions. What parts of the problem need further study?

3. Justification

The justification of the study project is an important part of any proposal. Studies are often expensive and time consuming. When funds are limited, it is especially important for the investigator to justify the proposed study carefully.

As you write the justification, it is usually helpful to consider the following questions, and then organize the responses into a few concise paragraphs:

- * Is the problem current and timely? Does the problem exist *now*?
- * Does the problem have life-threatening or serious morbidity consequences?
- * Does the problem affect (or potentially affect) a large number of people?
- * Does the problem relate to on-going program activities? Does the problem have implications for current programs?
- * Does the problem have broad social, economic, political, or health implications?
- * Is the problem viewed as a concern by many different people? A problem of concern to many different people – administrators, politicians, health

professionals, the general public – may be more likely to receive funding than one only a small group of researchers' view as a concern.

- * Have many studies already addressed the problem? Would another study add significant new information?

4. Goals and Objectives

Before a study is designed, the study's ultimate, long-term public health goal and its immediate, specific study objectives are written.

Ultimate Goals should be stated in terms of the potential impact or public health purpose of the study or service delivery program. Although goals are not as detailed as study objectives, they must be clear. Goals are stated in terms of:

- Broad social, economic, or health concerns.
- Change in policy decisions, service delivery programs, or individual health behavior
- Populations that may be affected

Study Objectives describe what will be demonstrated, tested, evaluated, confirmed, or compared. They communicate:

- What you plan to do
- Who will do it
- To whom it will be done
- When it will be done
- Where it will be done
- Where it will be done
- What you hope to learn

5. Study Questions or Hypotheses

All proposals should contain a formal and explicit statement of the study question(s) to be investigated or the study hypothesis(es) to be tested. Exploratory or descriptive epidemiologic study does not involve hypothesis testing; it is based on underlying questions. The study questions must be formally stated with clarity and specificity.

Analytic epidemiologic studies are designed to make predictions about the relationships between variables and therefore tests hypotheses. All proposals for analytic study must explicitly state the hypothesis(es).

A hypothesis is a statement (not a question) about an expected relationship between one or more independent variables and one dependent variable. The statement should proceed logically from your problem identification. In addition to stating the hypothesis(es), the proposal should also indicate:

- Under what conditions the hypothesis is expected to be true
- All potential intervening variables that may affect the dependent variable
- Operational definitions for all variables included in the hypothesis(es)

6. Study Design

The study design is determined by the primary purpose of the project. Therefore, the proposal should first indicate whether the study is *descriptive* or *analytic*. Note: remember that this proposal is for a **NON-RESEARCH** project.

A *descriptive study* is used when additional information is needed before being able to formulate specific hypotheses. Descriptive studies provide accurate baseline data on the occurrence or prevalence of a characteristic or event related to a health problem, and on the people who are affected and how they are affected.

An *analytic study* is used to explain the relationship between two or more variables by testing causal hypotheses that specify the relationship between the variables.

Once the primary purpose of the study is identified, you can select the study design. The type of design you choose is influenced by the purpose, the cost, and the nature of the problem to be studied. Possible designs include:

- Cross-sectional design
- Experimental design (randomized clinical trials)
- Cohort design
- Case-control design

7. Methods

The investigator must provide a thorough description of the methodology for selecting the subjects and for collecting the data. The content of the proposal's methods section will vary depending on the purpose of the study and study design, but this section should specify the study population, the type of data to be collected, and the data collection and quality control procedures.

The *Methods Section* should present step-by-step instructions for carrying out the research. This section should include the following:

- Definition of the population,
 - ❖ Include political, geographic, social, economic, and demographic identifiers
- Description of the sampling process, if applicable.
 - ❖ Identify the type of sample (e.g., simple random, systematic, cluster, multistage, non-probability)
 - ❖ Specify the sample size calculations
 - ❖ Describe the random assignment procedure for clinical trials
- Description of the type of data to be collected
 - ❖ Cases, controls, and comparison groups

- ❖ List all variables (i.e., independent, dependent, control, exposure, treatment, outcome, confounders, effect modifier) and state the conceptual and operational definitions
- Description of the data collection procedure
 - ❖ Indicate the data collection method(s) (e.g., structured or unstructured interview; focus groups; self-administered questionnaire; direct observation of behavior; service statistics; medical chart review; vital records, census data, or other secondary sources)
 - ❖ Describe the data collection instrument (e.g., questionnaire, medical records' abstract form). If the study uses a preexisting instrument, a copy may be appended to the proposal.
 - ❖ Discuss consent of participants and how it will be obtained. If an Informed Consent form is needed, a copy should be included in the proposal.
 - ❖ Discuss confidentiality of the data and how it will be maintained.
 - Discuss human subjects review, if applicable.
- Description of the procedures used to control data quality.
 - ❖ Describe how you will pretest the data collection instrument. Field tests should be conducted on a limited basis in an area outside the study area. All the study procedures should be followed.
 - ❖ Describe how you will reinterview subgroups of respondents. This is a common technique for testing the reliability of the instrument.
 - ❖ Describe how you will train interviewers and supervisors for data collection.
 - ❖ Describe plans for data control. Meticulous attention to detail is required by supervisors so that 1) all forms are completed according to the predesignated specifications; 2) errors are corrected; and 3) no forms are lost.
 - ❖ Describe whether you are using multiple sources of information to check validity of your data (such as an interview and a medical record).
 - ❖ Describe all other data quality checks.
- Description of the partners you will collaborate with on your study
 - ❖ This may include persons from the Ministry of Health, universities, Non-Governmental Organizations you work with, international organizations, or others

8. Analysis Plan

The analysis provides answers to the research questions. All proposals for epidemiologic studies contain plans for analysis. Although the analysis depends on the type of data collected, how the data are collected depends on the type of analysis anticipated. The sampling design is also frequently determined by the analytic needs. The analysis plan should deal with *data preparation* issues as well as *data analysis*.

Preparation of the Data

Before the actual analysis, the data must be checked for errors and put into a form that will allow it to be manipulated accurately and efficiently.

Tabulation. Indicate whether the data will be tabulated by hand, computer, or some other method.

Coding. The process of coding translates verbal responses into numerical codes that will facilitate data manipulation. Indicate whether coding is necessary and who will do it. If any of the variables in the study are obtained with open-ended questions, the need to code the responses to these questions may be mentioned.

Editing or cleaning the data. Editing ensures that no question on a questionnaire is omitted erroneously, that no illegal codes have been used, and that logical inconsistencies in the recorded responses are noted. Data may be edited in the field during the collection phase or in a central office after the fieldwork is completed. Data may be edited manually reviewing the questionnaires or forms on which responses were originally recorded, by using computer programs that find errors and inconsistencies in the data, or by reviewing tabulations produced by the computer. Computer editing may be structured to check each record as it is entered into the computer (this may be done in the field) or after all the records have been entered into the computer. The proposal should briefly state how the editing will be carried out.

Analysis of the Data

You may need to describe your plans involving the following categories:

Variable transformations

- ❖ Collapsing response categories
- ❖ Creating new variables
- ❖ Counting responses to a number of questions
- ❖ Constructing a scale/index that combines responses to multiple questions
- ❖ Creating temporary mathematical transformations

Descriptive Statistics – used to describe data quantitatively

- Univariate statistics include proportions, percentages, ratios, frequency distributions, graphic presentations, etc.
- Bivariate and multivariate statistics – to describe associations between variables

Inferential statistics – allow conclusions about a population from results obtained in a sample (using measures such as confidence intervals, tests of statistical significance)

Table shells – these may be useful in planning the data collection instrument and in visualizing how the data will be organized for analysis

9. Plans for Interpretation

Although data have not been collected or analyzed yet, the literature review and study design provide guidelines and constraints for interpreting the research results. The proposal should describe plans to interpret the results. Considerations include:

Generalizability. The generalizability of a study is a function of sampling and analysis procedures. The proposal should indicate the target population and any other populations to which the results can be generalized.

Limitations. All studies will have some weaknesses, for example, in the sample selection, questionnaire design, measurement, or analysis. The researcher's task is to keep the weaknesses at a minimum, to identify the limitations that do exist, and to inform the reader as to how the limitations preclude generalizability or how the problems may be overcome in future studies.

Potential contributions. The proposal should discuss the merits of the study, such as timeliness, public policy implications, contribution to scientific knowledge, and public health contribution.

10. Plans to Report Study Findings

The proposal should indicate what reports and other means of disseminating research findings are planned. Any (or all) of the following are appropriate for disseminating the results of the study.

- Progress reports
- Final report
- Publications
- Seminars, workshops, and conferences
- Discussions with policymakers and program managers

Questions that should be addressed when discussing dissemination of study results include:

- What specific parts of the research or data will be covered?
- At what stage in the study will the results be written, and by whom?
- How much time will be required to prepare the materials?
- Who will receive these materials?

Also include a short description of how you plan to communicate your results to your partners.

- What audiences need to know about your findings?
- How will you accomplish this?

11. Logistics

The Logistics are the resources, personnel, facilities, and budget required for the study. The proposal should indicate the anticipated cost of the study, the source of these funds, and how the funds will be allocated. The discussion about logistics should include:

- A description of the resources and facilities available for the study. Specify your computer facilities, secretarial or administrative assistance, office space, library facilities, and vehicles. Indicate whether other institutions will contribute resources and what proportion of the principal investigator's time will be devoted to the study (e.g., 100%, 60%, 20%). Many funding agencies prefer joint research projects and look favorably on proposals that show contributions from the applicant's home institution or other organizations.
- Any anticipated difficulty in obtaining scarce professional skills. Consultants or an advisory committee might be used if this need exists.
- A brief management plan that indicates who will be responsible for the budget, staff, field operations, data processing, analysis, and other components of the project. If several departments or institutions are collaborating on the project, indicate who will have overall responsibility and what would be the roles or contributions of the different departments or institutions.
- A clearly outlined, realistic budget that lists each cost item and its components. Arrange your cost items under the following major headings:

Payments to personnel (stipends for yourself are not admissible), such as:

- Interviewers
- Computer programmer
- Keypunchers and coders
- Clerical staff
- Other

Supplies and Equipment.

- Reproducing questionnaires or other forms
- Office supplies
- Telephone costs
- Mailing costs
- Computer time or purchase
- Report printing and distribution

Travel. This category should only include travel necessary to complete the study and to initially distribute the results.

- Vehicle rentals
- Gasoline/Petrol
- Lodging for interviewers during fieldwork

Miscellaneous costs. Separate cost by year if the study will require more than one year.

12. Work Schedule or Timeline

The steps and their sequence in the entire study process should be outlined. A corresponding calendar should indicate the amount of time each step will require. The steps might include:

- Selecting the sample
- Drafting the questionnaire
- Training interviewers and supervisors
- Pretesting the questionnaire
- Revising the questionnaire
- Printing the questionnaire
- Carrying out fieldwork (interviews)
- Coding the data
- Key punching the data
- Editing the data
- Tabulating the data
- Analyzing the data
- Writing the final report
- Printing the final report
- Presenting the research findings at conferences

13. Bibliography for the Proposal

The proposal should include a bibliography that contains the sources cited in the text of the proposal (found in the problem identification and justification, or in the literature review). Important references that were not cited in the text may also be listed in the bibliography, including methodologic sources.

14. Appendices to the Proposal

Documents such as curriculum vitae and questionnaires receive close scrutiny by reviewers. Therefore, careful attention should be given to the organization and presentation of documents that are not placed in the text of the proposal. Appended documents may include:

- Curriculum vitae of principal investigators
- Information on institutional affiliation of researchers
- Sample of data collection instrument
- Informed consent form
- Letters of endorsement for the study
- Other information relating to the study