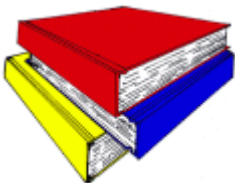


THE RESEARCH PROPOSAL



PUTTING IT ON PAPER



Guidelines for Writing a Research Proposal

When writing your proposal, follow the following template:

1. **Title.** Give your proposal a working title.
2. **Specific Aims and Hypothesis(es).** Indicate the significance of your research topic, and state the nature of the research problem you wish to examine. Then, state the hypothesis(es) to be tested and the specific aims of the research proposal. You want This section is also called Statement of Problem or Goals and Objectives.
3. **Background and Significance.** Describe briefly the background to the proposal, including relevant studies by other investigators. State concisely the importance of the research described in this proposal by relating the specific aims to broad, long-term research objectives in the field.
4. **Research Design and Methods.** Provide a description of:
 - State the research design and the specific procedures to be used to accomplish the specific aims;
 - Methods explain procedures used to achieve the Specific Aims.
 - Potential experimental difficulties should be discussed together with alternative approaches that could achieve the desired aims.
5. **Adverse Event Reporting.** Adverse event data collection and reporting are required as part of every clinical trial and are done to ensure the safety of patients enrolled in the study as well as those who will enroll in future studies using a similar intervention. Adverse events are reported in a routine manner at scheduled times during a trial. All adverse events must be reported to the St. Vincent Internal Review Board with out delay.
6. **Literature Cited.** At the end of the research proposal provide citations for any published worked referenced in the proposal. Each citation must include names of all authors, titles, book or journal, volume number, inclusive page numbers, and year of publication.
7. **Appendix.** The appendix should include copies of all materials that will be provided to study participants and any material that contributes to the proposal.

Research Proposal Guidelines

These guidelines are a detailed discussion of what should be included in the sections outlined in the proposal template.

General Set-up:

First, several general guidelines are important to remember:

- Proposals must be submitted by the principal investigator.
- Proposals should be crisp and clear
- Do not use a font size smaller than 12 pt. (Times New Roman or Arial)
- Use paragraph headings in bold font
- Pagination (page __ of __) in the center at the bottom of each page

Title:

The title should be appropriate and convey significant information about the specific topic of your research proposal. A good title should be short, accurate, and concise. It should make the central objectives and variables of the study clear to the reader. 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 will be investigated. For example, a poor title would be: “Correlates of physical activity in individuals with diabetes.” A better title would be: “Correlates of physical activity levels in a sample of urban African Americans with type 2 diabetes” (Pearte CA et al., 2004).

Specific Aims:

Preparation of a research proposal should start with the Specific Aims; the rest of the proposal merely amplifies what is presented here. **ONE PAGE IS RECOMMENDED.**

Write the Specific Aims page in five pieces. The aims are then perfected, trimmed, and merged. The 5 pieces are: introduction, general goal/significance, a theoretical framework or model, hypothesis(es), and specific aims.

1. **Introduction.** The Introduction should briefly set the context of your research interest, aiming to indicate the significance of your research topic, and state the nature of the research problem you wish to examine. This is the “Big Bang” – the one that begins it all. Similar to debates, you can use one sentence, statement or questions as a jump-off point to a complete body of research. This opener, though, should not be too broad. For example, “Drinking too much coffee is bad for health” is too generalized. What is covered in the term “health”? What is considered “bad”? Is this from a social, psychological or medical point of view? Does this statement apply to all types of coffee (including decaffeinated coffee)?

2. **General goal and significance.** The problem is stated and is shown to be important. This must be done in one or two sentences. An indication of the direction of the study is expressed in the goal statement, which should be broad enough to give the impression that this study is part of a larger research plan that will continue beyond the bounds defined in the Specific Aims. A long-term goal may be identified generally as simply the alleviation of the problem. In the opening statement it is essential to avoid using abbreviations.
3. **A theoretical model.** Having identified the problem, present a broad theoretical construct of a model to which the problem can be related. In disease-related research, the model pertains to pathogenesis. Theory can add great depth to the proposal. Its absence is a subtle red flag, and alerts the reviewer to the possibility that the proposal will lack focus and depth.

One of the most common complaints about weak proposals is that they are too “diffuse.” This usually means that the Specific Aims are not sufficiently closely interdependent. Diffuse proposals often lack a theoretic framework that would serve to keep the work focused.

4. **Hypothesis(es).** Having established the problem and a logical structure within which it can be considered, one or more specific hypotheses should be stated. This is the most important part of the Specific Aims section, and is often missing or stated in such general terms as to be useless.

Unless a specific hypothesis can be stated and tested, research is nothing more than a fishing expedition. A proposal is strengthened if a hypothesis is clearly identified, if it relates logically to a broad theoretic model, and if the proposed experiments will unequivocally assess its veracity.

A hypothesis worthy of consideration can be tested directly or gives rise to corollaries or predictions that can be tested. Untestable hypotheses are worse than useless; they are destructive in that they may consume time and effort without a concomitant advance of knowledge. Too many hypotheses signal lack of focus. A single important hypothesis is best; most proposals list two, or sometimes three (four is too many).

Example:

An untestable and vague hypothesis: Heart failure patients with prompt follow-up after hospitalization will have better outcomes.

A more specific hypothesis: Heart failure patients seen within 72 hours of discharge will be readmitted less and continue taking their prescribed medications than patients seen after 72 hours.

5. **State the Specific Aims.** Specific Aims are tests of the hypothesis(es) presented in terms of experiments or groups of experiments. These should be listed numerically and should be reiterated verbatim and in order in the Research Design section of the proposal. Specific Aims should be just that—specific. They must be brief and indicate the general nature of the technology used (but do not discuss the actual methods here).

Ideally, the reason for each of the Aims is obvious from consideration of the hypothesis and its corollaries. There is never enough room on this page to explain fully the rationale of each Aim, but this is done in exhaustive detail later in the proposal. It is only necessary that each Aim fit within the structure of the theory. Avoid editorializing in this section. Do not use references. Three to four Specific Aims are usually enough!

Background and Significance

Briefly sketch the background to the present proposal, critically evaluate existing knowledge, and specifically identify the gaps in which the project is intended to fill. State concisely the importance of your research by relating the Specific Aims to the broad, long-term objectives and to health relevance. 2-3 PAGES RECOMMENDED.

The project must be perceived to be important, interesting, and likely to succeed. General ideas concerning the scope of the project were presented as unsupported statements in the Specific Aims, so it is the purpose of the Background section to provide the missing support through expansion and judicious reference to the literature. The prose must be sharply focused to show the following:

1. The project is *important*. It relates to significant human disease or to significant deficit in our knowledge of an important biologic process; the results of the hypothesis tests will have a predictable impact on theory and/or ultimately lead to improvement of the human condition.
2. The project is *interesting*. The study can be related to a general theoretical model that is the subject of widespread interest; important areas within the model that are unproven, controversial, or ambiguous are addressed.
3. There is high probability of success. Specific hypotheses to be tested can be identified as part of the theoretical model; tests of the hypotheses (Specific Aims) are feasible, definitive, and within the range of your expertise.

It is essential that this section be outlined before it is written. The outline should provide titles for each paragraph. When the outline is complete, there should be an obvious logical connection from one paragraph to the next. The logic of the connection is stated in a sentence that should be added to the outline. These sentences may eventually appear in the finished document as transition sentences between paragraphs.

In the background you should:

- Review the appropriate literature to indicate the significance of your research,
- Describe the preliminary studies that you have completed, and
- End with a brief statement of what is known, what is not known, and a clear, specific description of the research question(s) you propose to investigate.

Significance of research 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 non-conclusive evidence. Moreover, there may be very conclusive evidence for knowledge considered to be established, but you question the accumulated knowledge because of certain events that you intend to subject to verification. It is at this point where you define 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 way 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 justification 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.

Research Design and Methods

Research Design is very different from Methods. Research Design is interesting, logical, and organized. The design of a project involves conceptualization of a logical sequence of experiments that test specific corollaries of an important hypothesis. Design of individual experiments can be clever or innovative, intuitive, powerful, straightforward or complex, naïve or sophisticated, effective or inappropriate.

Methods are dry as dust. Methods are a cookbook recitation of the intimate details of a procedure. They are quantitative, precise, often repetitive, often completely familiar to

the reviewer and lengthy. Methods are absolutely necessary to answer simple but vital questions concerning technique that will come up as the proposal is reviewed.

The proposal that mixes Research Design with Methods is frustrating and difficult to read. It is much more friendly to provide an initial design section that communicates everything the reviewer needs about the logic and conduct of the project, including numbers and types of samples, animals, or experimental subjects and controls. This should be written to be informative and to be scanned quickly. A study flowchart of events is also an effective high-level tool. The Methods section should provide all the details about procedures listed in the design.

Research Design

The Research Design section should answer the question “What will be done to accomplish the Specific Aims?” It should also clearly state the type of study that will be conducted and provide a detailed explanation of its 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.

If you propose to conduct an experimental study, the proposed intervention or program should be thoroughly described. A tentative timeline can also be helpful. You 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.

This section should also clarify where research activities will be conducted, describe how you will address each specific research question, and identify control and experimental groups. The goal of this section is to communicate this information in as brief and logical a sequence as possible. Rigorously exclude any description of the methods by which things will be done.

Throughout this section, clearly indicate:

- What specific question is addressed by each proposed Aim
- Potential difficulties
- What results you expect to find
- How results would be interpreted
- A tentative sequence or timetable for the investigation

This section should be complete enough so that the reader understands what the intervention/treatment entails, without having to read any other material.

Methods

The goal of the Methods section is to convey a maximum of information about the procedures to be used. It should provide at least as much detail as a publication, and for difficult procedures a great deal more. Describe your methods and procedures in sufficient detail so that someone else could complete the proposed research by simply referring to your proposal and the cited references. In other words, too much detail cannot be given.

The Method section explains how you will conduct your research and explains the procedures that will be used to achieve the Specific Aims. 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 research design and the techniques and procedures used to achieve the proposed hypothesis(es). A description is given below of what the investigator is expected to specify in the Methods section.

The following subheadings are suggested for the Methods section.

Subject Characteristics

- Provide a detailed description of the proposed involvement of human subjects and/or human derived materials.
 - Anticipated number
 - Age range
 - Health status
 - Recruitment site(s)
 - Summarize gender and racial/ethnic composition of the subject population.
 - Identify inclusion and exclusion criteria. If a gender and/or minority are excluded provide a clear rationale for the exclusion.
 - Explain the rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, prisoners or others who are likely to be vulnerable.
- Explain how you will attempt to get a representative sample of the population to which you intend to generalize.
- Identify sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether this information will be obtained specifically for research purposes.
- If human derived materials from non-living subjects are to be used, state whether they are medical records, teeth, serum samples, tissue blocks, etc. State where they were obtained, how long they will be used, how they will be discarded, who will have access to the materials, etc.

Subject Recruitment and Informed Consent Process

- Describe the recruitment procedures and any payment that may be made.
- Describe plans for the informed consent process. Include the following:
 - 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
 - The methods of documenting consent
 - Include procedures for obtaining parental consent and child assent when subjects are minors, using witnesses or translators.
- Explain how informed consent will be obtained and documented if a potential subject does not read or write.
- If warranted, explain how informed consent will be obtained if subjects who do not speak or read English will be involved.

Intervention/Treatment Plan

This section is 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, e.g., before and after, where assessment is made of results attributable to the intervention. If subjects will be randomized, describe how the randomization process will be conducted.

A full description of the intervention/treatment plan and an explanation given of the activities in their order of occurrence should be provided. A detailed description of required clinical, laboratory, and disease evaluations required prior, during and after the intervention must also be addressed. It is essential that the description answer four fundamental questions:

1. Who will be responsible for the intervention?
2. When and where will it take place?
3. What activities will be performed, and with what frequency and intensity?
4. How will the intervention be implemented?

Device or Drug Studies

For device or drug studies, provide drug or device information and address dose modifications for toxicities. If the intervention includes surgery, pathology, or a similar procedure, guidelines for the procedure(s) must be given.

Consultants

If you will consult others you need to:

- Describe who the consultants are, e.g.,
 - Statistician
 - Medical specialist
 - Librarian
- Clarify what role the consultant will serve
- Discuss the areas in which the consultant will participate
- Explain how the consultant will enhance the research project

Operational Definition of Variables

Operationalization is a process that will vary according to the type of research and research design. However, variables should be clearly defined and appropriately operationalized, in other words, you should clearly describe each variable:

- What type of variable is being considered
- How the variables will be measured
- How variables will be presented (quantitative and/or qualitative), indicating the analytic models and techniques (statistical, non-statistical, or analytical techniques for non-numeric data, etc.)
- Be specific on timing and units of measurement, and what constitutes “Yes” and “No”, and what other options might come up.

You 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. Proposals are considered incomplete if their operational aspects are vaguely formulated.

Data Collection

- Procedures for data collection, for e.g.,
 - Pop survey
 - In-depth interviews
 - Non-participant observation
 - Focus group dynamics
 - Content analysis
- Who will collect the data
- How and where the data collection will occur
- Instruments used, e.g.,
 - Questionnaire
 - Interview guide
 - Observation recording form
 - Guide for focus group moderator
 - Content analysis guide

- Methods for data quality control
- Anticipated Outcomes
- Plans for document storage

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 also 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 person responsible for compiling the information, and controls for the instruments).

If the use of secondary data is required, you need to 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 the information.

Data Analysis

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

- Patient accrual
- Study duration
- Analytic endpoints
- Software packages that will be used and their anticipated applications
- Statistical analysis and power
- Methods and models of data analysis according to types of variables
- Programs to be used for data analysis
- Interpretation

Adverse Event Reporting

Reporting requirements may include the following considerations:

- Whether the patients has received an investigational or commercial agent;
- The characteristics of the adverse event including the grade (severity), the relationship to the study intervention (attribution), and the prior experience (expectedness) of the adverse event;
- The Phase (1, 2, or 3) of the trial;
- Whether or not hospitalization or prolongation of hospitalization was associated with the event.

Literature Cited:

Do not scatter literature citations throughout the text. List them at the end of the Research Design and Methods section. Each literature citation must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. Make every effort to be judicious in compiling a relevant and current list of literature citations; it need not be exhaustive.

An average proposal should probably include no more than about 75 referenced papers. References to new areas of research are often controversial but must be cited to show familiarity with the current work in the field. Avoid listing more than three references to support a statement. More than this number is usually just padding.

It is seldom necessary to cite directly any literature that is older than 10 years because it will usually be included in recent reviews of the subject. It is more effective to limit references to highly pertinent recent papers, and to present these in more detail with thoughtful discussion of their relation to the proposed project.

Never cite a paper that has not been carefully read in its entirety. The availability of library searches and computer printouts of abstracts of papers published in selected areas of research often leads to citations based on reading only an abstract. But many abstracts are incomplete and/or misleading or may represent shoddy work, even though the paper may originate in the laboratory of some "Eminent Investigator."

The citation format is left to the discretion of the investigator. Space limitation dictates that citations be numbered and so entered in the text. Superscripts take up the least space but make for a sloppy document if they overlap the preceding line of type. A small font should be used for superscripts; a 6- or 8-point font is preferred. Present the complete citations for all the factual material you refer to in the text of your proposal.

Appendix:

The Appendix should include copies of all materials participants will see and/or respond to; it may include questionnaires, photographs, or other materials that do not copy well. Copies of all instruments to be used (questionnaires, interview guides, moderator guides, registration forms, etc.) should be included, and you should indicate their stage of preparation. Material submitted in an appendix should be publication quality if at all possible. Do not submit graphs drawn by hand or substandard micrographs. It is essential that every item in the appendix be an important contribution to the proposal. This contribution must be noted in the proposal text.

Citations:

Information presented in this document was taken from several sources, including, but not limited to:

Ogden TE and Goldberg IS. *Research Proposals: A Guide to Success*, 2nd ed. New York: Raven Press.

Pan American Health Organization. Guide for Writing a Research Protocol. 2002. Created May 24, 2002. <http://www.paho.org/English/HDP/HDR/RPG/Research-Protocol-Guides.htm>

Riegelman RK. *Studying a Study and Testing a Test*. Philadelphia: Lippincott Williams & Wilkins, 2000.

Peat JK. *Health Science Research: A Handbook of Quantitative Methods*. London; Thousand Oaks: Sage, 2002.