

Chapter 32 “Writing a Research Proposal”

From “Foundations of Clinical Research: Applications to Practice” by Leslie Gross Portney; Mary P. Watkins (2007)

The initial stages of the research process include development of the research question and delineation of methods of data collection. The success of the project depends on how well these elements have been developed and defined in advance, so that the proper resources are gathered and methods proceed with reliability and validity. The plan that describes all these preparatory elements is the research proposal. The proposal describes the purpose of the study, the importance of the research question, the research protocol and justifies the feasibility of the project.

The proposal can serve several purposes. First, it represents the synthesis of the researcher's critical thinking and the scientific literature to ensure that the research question is refined enough to be studied, that the assumptions and theoretical rationale on which the study is based are logical and that the method is appropriate for answering the question. Second, the well-prepared proposal may constitute the body of a grant application when external funding is required. Third, it is part of an application for review by peer or administrative committees. This is the document that will be carefully scrutinized by the Institutional Review Board (IRB) (see Chapter 3). Fourth, the proposal enhances communication among colleagues who may be co-investigators and with consultants whose advice may be needed. Finally, the careful, detailed account of the study procedures serves as a guide throughout the data collection phase to ensure that the researchers follow the outlined rules of conduct. The research proposal, therefore, is an indispensable instrument in initiating and implementing a project.

When proposals are written as part of a grant application for funding from foundations or government agencies, the researcher must obtain the guidelines of the agency to which the proposal will be submitted. Generally, requirements and components of a proposal will be the same for grant applications as they are for academic and clinical institutions; however, to write a successful grant application, the researcher must understand the interests of the funding agency, the extent of available funds, the deadlines for submitting proposals, and the proper format of the application.

The purpose of this chapter is to discuss the process of developing and writing a research proposal. The exact format of the proposal will depend on the requirements or instructions of the individuals, clinics, faculty or agencies that will review the project.

The problem statement, therefore, presents a rationale for the specific question being addressed by the project. In the preceding example, the authors have created a rationale for examining the difference between the structured specialist community program and standard care. No single project can be expected to solve a problem in its entirety. On the other hand, each project should clearly contribute to the solution. Each study expands the evidence that can be used to support the body of knowledge related to the research problem. The content of the opening section of the proposal should clearly demonstrate this contribution.

Purpose, Hypotheses and Specific Aims

In a brief statement, the researcher must state precisely what the project is expected to accomplish. The purpose of the study should follow clearly from the justification presented earlier. If the research is to be experimental or correlational, the purpose is translated here into research hypotheses. Research hypotheses are stated in positive terms; they reflect the expectations of outcome. "Null" hypotheses that serve a statistical function do not belong in the text, unless the purpose of the research is specifically to show that no relationship exists between variables. If the research is descriptive in nature, the author will state the characteristics or behaviors that will be documented in this work and what questions the data will answer about the target population. Many granting agencies require a statement of specific aims or objectives for a project. For instance, a study's objectives might be to add to the body of knowledge in a certain content area, to test a theoretical proposition, to demonstrate differences between certain treatments to develop more effective and efficient intervention strategies, to document the reliability of an instrument, or to establish the relationship between specific variables as a basis for making treatment planning decisions. These objectives are derived from the research hypotheses or descriptive questions. Objectives help reviewers focus the description of methods and will often help the researcher guide the discussion of results when the study is completed.

Proposals for qualitative research may need to include explanations of the research approach, especially when those who will review the proposal are unfamiliar with naturalistic inquiry. The researcher should include specific reference to the form of qualitative research (for example,

ethnography or phenomenology), including assumptions about the nature of knowledge and reality that are relevant to the area of study.⁴

Background

The presentation of background information includes the theoretical rationale for the study and pertinent facts, observations or claims that have led the investigator to the proposed research question. This information is derived from the literature review (see Chapter 7) and from previous or related work done by the investigator. Funding agencies look favorably on projects that are built on previous work by the investigator.

The literature review is difficult to present concisely, and much effort is usually required to integrate published material to make relevant points. While preparing for a project, the researcher will have read and catalogued many references, typically many more than will or should be included in the written proposal. Authors must continually ask, "Is this reference or point of information directly related to this study?" "Does it contribute to the rationale or clarify the basic assumptions that underlie the research question?" If the answer is "No," then the reference should be set aside or discarded. When the references have been selected, they should be organized by topic areas to facilitate organization of the paper.

The presentation of the review of literature includes the main points that serve as the background of the proposed study. A meaningful review of literature provides a clear representation of the author's thought processes in developing the proposed study. It is not simply a series of abstracts of papers on the topic. The author must convey an integration of content that supports the need, importance and rationale for the proposed study. The need and importance of the proposed study are defined in relationship to existing clinical or scientific reports. The first elements of the review may include relevant epidemiological factors, demographics, the impact of the research issue on health care policy or practice and the potential impact on patients. For instance, for the example cited earlier, the investigators might focus on the rising costs of care resulting from the increased incidence of stroke, and the potential psychosocial advantages of the patients' early return to community living.

The major portion of the background focuses on prior research that has been done to address the same or related questions, reflecting current knowledge or lack of knowledge. This includes a synthesis of consistencies and conflicts found in prior reports. The possible reasons for inconsistencies and identifiable limitations of previous studies should be elucidated to provide further evidence that more study is required. The content of this section should show the logic for selecting subjects, selecting the variables to be studied and the methods of measurement. This section should end with a summary of the facts, problems, or controversies found in the literature and the relevant perspectives of the researcher that lead directly back to the specific need and stated purpose of the proposed study.

Method

The method section is probably the most important part of the proposal, and should be both concise and complete. The author should include enough detailed information so that reviewers can judge the soundness of the work, so that members of the institutional review board can determine exactly what the subjects will be asked to do and so that the researcher can determine the feasibility of the study. The opening section identifies the overall study design that will be employed to test the research hypothesis or answer the research question.

The details of the research methods are usually presented in four subsections: Subjects, Materials, Procedures, and Data Analysis.

Subjects. The description of subjects used in human studies is extremely important because of the inherent variability among them and the vast number of extraneous factors that may affect human behavior or performance. The author must describe who the subjects will be in terms of inclusion and exclusion criteria, how many and from where subjects will be recruited, how they are to be selected, and the method by which they will be assigned to groups for the study. Characteristics such as age, gender, disability, diagnosis and duration of hospitalization should be defined if they are relevant to the study. The author must include all, and only, those factors that could influence the results and the ability to generalize the findings to the target population or to compare findings with other similar studies. Funding agencies and institutional review boards generally require a power analysis to demonstrate the appropriateness of the proposed sample size.

Materials. Materials refer to the equipment, instruments or measuring tools that will be used in the study. Materials should be described according to important characteristics such as brand name and model and should be documented for reliability and validity. If measurement tools are new, relatively unknown, or developed by the researcher, they should be described in sufficient detail and a figure

should be included. If the measurement tool is a survey, the entire document may be presented as an appendix to the proposal or a set of sample questions may be included in the narrative.

Procedures. The procedures section describes precisely what is to be done from beginning to end of the investigation, in chronological sequence. Procedures also include how, and by whom data are to be collected. Operational definitions should be provided for independent and dependent variables. If these procedures are extensive and lengthy, they may be briefly described in the text with references to appendixes that will present the details in full. The researcher should include strategies for controlling extraneous variables.

In qualitative study, the proposal should include how the researcher will interact with subjects, describing the kind of data that will be collected (for example, field notes, audio tapes, video tapes, or transcriptions).⁴

A chart or flow sheet, presented in tabular form, will serve to summarize the procedural sequence. Figure 32.1 illustrates the timetable for a hypothetical 2-year study. The study is a pretest-posttest design with subjects randomly assigned to two treatment groups. The intervention period for each subject lasts 6 months. Outcome data will be collected initially, each month for 6 months, and 9 months after the initial evaluation of each patient. The last patients will be admitted to the study in Month 15; their treatment period, lasting 6 months, will end in Month 21, and their follow-up assessment will be made 3 months later, in Month 24. Such a display of the "work schedule" will assist reviewers in evaluating the feasibility of the investigation in terms of time and available funding.

Data Analysis. The plan for data analysis should outline specific procedures for recording, storing, and reducing data and for statistical analysis. Reviewers will examine both descriptive and analytical methods to determine their appropriateness for the design of the study and the type of measurement. It is often helpful to obtain the services of a statistician to be sure that this section is accurate and complete. The funding agency will probably have a statistician review it.

Proposals for qualitative studies should include descriptions of how notes will be transcribed and reconstructed.⁴ The specifics of coding and sorting data may evolve as the project unfolds, but the researcher should discuss the intended format and how the process will be developed. Methods of establishing reliability and validity of data should be included (see Chapter 14).

References. The final part of the narrative portion of the proposal should be a listing of literature cited in the paper. Some agencies require the use of a specific bibliographic style, but often this is left to the discretion of the researcher.

Documentation of Informed Consent

A copy of the informed consent form must accompany the proposal when subjects will be directly involved in the study. The informed consent form may not be required for secondary analysis studies. Funding agencies and sponsoring institutions may require IRB approval before a proposal is submitted and reviewed. The time delays inherent in obtaining this approval must be built into the timetable for submitting the proposal. Documentation of IRB approval must accompany the proposal. The process and elements of obtaining informed consent are discussed in Chapter 3.

PLAN FOR ADMINISTRATIVE SUPPORT

Budget

Every proposal, even those written for student research, should include an estimate of projected expenses, to demonstrate the feasibility of the project. For a grant application, the budget is an extremely important part of the proposal, and must be complete and detailed according to the instructions of the funding agency. Students may need to show how resources will be made available to them if there are no funds available for the project. Many schools provide small grants that will assist students with their thesis projects.

The format and content of the budget will vary depending on the type of research proposal. Generally, the budget is presented by category as a summary of totals and as an itemized budget. For grants that are expected to run more than one year, only the first year's budget is itemized, and summaries of projected expenses for additional years are provided. A narrative section, called the budget justification, should be included to explain the projected costs in each category. The typical budget categories are personnel, equipment, facilities, supplies and travel.

The itemized personnel budget identifies the names of each individual who will participate in the study, their proposed title (such as principal investigator, consultant, statistician, research assistant, secretary), the salary for each individual and the percentage of full-time or number of hours that will be devoted to the project. Dollar amounts may be based on percentage of the individual's full-time salary or an hourly wage for a specified number of hours. Some personnel may be asked to participate in the project with no remuneration. These individuals should also be listed, showing no

salary request. Associated fringe benefit amounts are listed separately based on the total amount of projected salaries and wages. Reviewers will scrutinize the personnel budget particularly to evaluate the appropriateness of the time commitment of each participant. The budget justification should explain the responsibilities of each participant and should show that the personnel will realistically be able to achieve the desired outcomes.

Equipment costs are given for all equipment that will be purchased with grant funds. Costs should reflect current prices and any charges related to installation, calibration and maintenance. Most granting agencies define a threshold cost for "equipment" as having an extended life expectancy of at least 3 to 5 years. The narrative should provide details of equipment, such as manufacturer, model number and special accessories that are needed for the study. The researcher should indicate if some of the necessary equipment is already available, to show the funding agency that the project can be completed with some contribution by the researcher's institution.

The budget may include a request for funds for alteration or renovations to facilities. If space must be altered to accommodate equipment or to provide a work area, the contractors' estimates should be confirmed before specifying those costs in the budget. Explanations of all construction costs should be provided in detail, justifying why they are necessary for the study.

The category called supplies usually refers to consumable materials as opposed to capital equipment. Specific quantities of these supplies should be given with justification. A category of "other expenses" may also be included to account for miscellaneous items, such as telephone costs and photocopying. Depending on the nature of the project and the regulations of the funding agency, travel expenses may be budgeted. Travel to and from the institutional "home base" to collect data is certainly part of conducting a project and is likely to be an acceptable expense. Travel to meetings where data may be presented is more indirectly related to the project, but can often be justified. Travel costs may also be applied to patients who must be transported for purposes of the research.

All of the preceding budget categories are defined as direct costs. Indirect costs relate principally to the overhead charged by the sponsoring institution for administrative activities, facility maintenance and any other support services. Funding agencies usually limit the amount of support that may be used for indirect costs based on some defined percentage of the total budget. In cases where the customary institutional charge exceeds the set limit, the budget narrative should specify the manner in which such a discrepancy will be handled. In some cases, granting agencies will negotiate this percentage. The total budget for the project is the sum of all direct and indirect costs.

In every institution where research is conducted, there is an administrative officer responsible for grants and contracts. This individual will be able to assist researchers with the general "anatomy" of a proposal budget and will provide information about fringe benefits, indirect costs and institutional support. Consultation with this individual is essential and should begin early in the process of developing a research proposal budget. The administrative officer must sign off on the proposal before it is submitted, reflecting institutional approval of the proposed project.

Resources and Environment

Many funding agencies and academic or clinical institutions will also ask for information regarding existing resources for carrying out the proposed project. The investigator will be asked to describe available laboratory facilities, equipment, clinical sites, computer capability, office space and so on, to demonstrate that the project is feasible within the institution's environment. The areas in which data collection will take place should be described, as should the areas where equipment will be housed. In addition, administrative support services may need to be described. Documentation of secretarial or technical assistance or the need to acquire such support will be evaluated by reviewers in regard to the feasibility and justification of the applicant's budget request.

Personnel

Identification of the investigators and their qualifications is an important element of a proposal, especially when external funding is being sought. This will probably not be a factor in student research, except where expert assistance is required for carrying out parts of the project. Funding agencies will examine investigators' education, experience, track record of research and prior publications to determine that they have appropriate qualifications. This information is most often provided in the form of biographical summaries for each person working on the project. Some institutions offer a variety of funding programs and the eligibility requirements differ for each program. For example, the Arthritis Foundation offers several programs ranging from postdoctoral fellowships for individuals with 3 to 6 years of research experience to traineeships for supporting the research of individual health professions." Grants through the national institutes of Health usually require that someone with an MD or PhD and research experience act as primary investigator. Foundations that

support new investigators often require that an experienced, competent researcher supervise the proposed work. Because of these kinds of criteria, the inclusion of information about the participants in a proposed study is essential to the process of evaluation by an agency or foundation.

PRESENTATION OF THE PROPOSAL

Style

The research proposal is a forward-looking document. The researcher's thinking begins with the present, acknowledges and draws from the past, but primarily leads to the future. Therefore, the statement of the problem is written in the present tense, the background is written in the past tense, and the method (which is the proposed research) is written in the future tense.

The actual format required for the proposal varies among agencies and schools. The researcher must follow the specific instructions provided by the sponsoring agency. The method of citing references should be consistent throughout, and tables and appendixes should be clearly labeled and cited in the text.

The tone or mood of the document should be positive, persuasive and scholarly.

The researcher must convince reviewers that the proposed research is important, that there is a need to conduct the proposed research, and that the research team has the knowledge and ability to accomplish the study objectives. Phrases such as "perhaps the results will contribute" and "we hope to demonstrate" convey hesitation and insecurity. Conversely, the use of superlatives, implying that this work will be the greatest of all, will detract from the substance. A proposal that is sensible, factual and realistic will receive the attention it deserves.

COMMENTARY -

Review, Revise, Edit, Revise, Review

Even the most experienced researcher will find writing a proposal challenging. For those with less experience, the empty page may seem like an insurmountable hurdle. The best way to get started is to dive in, with the clear understanding that there will be several drafts and revisions before the proposal is ready for submission." The proposal will not necessarily be written in the order that it will later be read; for example, the abstract is presented at the beginning, but may actually be written last. Before the "final" version is ready, one final step should be taken: enlisting others to read the whole proposal. Graduate students have "built-in" readers; this is one of the responsibilities of thesis and dissertation advisory committees. Those who are not students should seek three kinds of individuals to review the proposal. One who is knowledgeable about the topic and the relevance of the project should be asked to evaluate the appropriateness, accuracy and thoroughness of the presentation. Another who understands research design and methodology will concentrate on the validity of the research methods relative to the research question and specific aims. The third should be someone who is unfamiliar with the subject matter and who will react to the readability of the paper. All three may notice inconsistencies, instances of unnecessary professional jargon or redundancy. This kind of preliminary review by colleagues is valuable for inspiring the researcher's confidence that the proposal is ready for formal review and subsequent successful implementation.