

How to prepare a Research Proposal

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Abstract

Health research, medical education and clinical practice form the three pillars of modern day medical practice. As one authority rightly put it: 'Health research is not a luxury, but an essential need that no nation can afford to ignore.' Health research can and should be pursued by a broad range of people. Even if they do not conduct research themselves, they need to grasp the principles of the scientific method to understand the value and limitations of science and to be able to assess and evaluate results of research before applying them. This review paper aims to highlight the

essential concepts to the students and beginning researchers and sensitize and motivate the readers to access the vast literature available on research methodologies.

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Most students and beginning researchers do not fully understand what a research proposal means, nor do they understand its importance.¹ A research proposal is a detailed description of a proposed study designed to investigate a given problem.²

A research proposal is intended to convince others that you have a worthwhile research project and that you have the competence and the work-plan to complete it. Broadly the research proposal must address the following questions regardless of your research area and the methodology you choose: What you plan to accomplish, why do you want to do it and how are you going to do it.¹ The aim of this article is to highlight the essential concepts and not to provide extensive details about this topic.

The elements of a research proposal are highlighted below:

1. Title: It should be concise and descriptive. It must be informative and catchy. An effective title not only pricks the readers interest, but also predisposes him/her favorably towards the proposal. Often titles are stated in terms of a functional relationship, because such titles clearly indicate the independent and dependent variables.¹ The title may need to be revised after completion of writing of the protocol to reflect more closely the sense of the study.³

2. Abstract: It is a brief summary of approximately 300 words. It should include the main research question, the rationale for the study, the hypothesis (if any) and the method. Descriptions of the method may include the design, procedures, the sample and any instruments that will be used.¹ It should stand on its own, and not refer the reader to points in the project description.³

3. Introduction: The introduction provides the readers with the background information. Its purpose is to establish a framework for the research, so that readers can understand how it relates to other research.⁴ It should answer the question of why the research needs to be done and what will be its relevance. It puts the proposal in context.³

The introduction typically begins with a statement of the research problem in precise and clear terms.¹

The importance of the statement of the research problem:⁵ The statement of the problem is the essential basis for the construction of a research proposal (research objectives, hypotheses, methodology, work plan and budget etc). It is an integral part of selecting a research topic. It will guide and put into sharper focus the research design being considered for solving the problem. It allows the investigator to describe the problem systematically, to reflect on its importance, its priority in the country and region and to point out why the proposed research on the problem should be undertaken. It also facilitates peer review of the research proposal by the funding agencies.

Then it is necessary to provide the context and set the stage for the research question in such a way as to show its necessity and importance.¹ This step is necessary for the investigators to familiarize themselves with existing knowledge about the research problem and to find out whether or not others have investigated the same or similar problems. This step is accomplished by a thorough and critical review of the literature and by personal communication with experts.⁵ It helps further understanding of the problem proposed for research and may lead to refining the statement of the problem, to identify the study variables and conceptualize their relationships, and in formulation and selection of a research hypothesis.⁵ It ensures that you are not "re-inventing the wheel" and demonstrates your understanding of the research problem. It gives due credit to those who have laid the groundwork for your proposed research.¹ In a proposal, the literature review is generally brief and to the point. The literature selected should be pertinent and relevant.⁶

Against this background, you then present the rationale of the proposed study and clearly indicate why it is worth doing.

4. Objectives: Research objectives are the goals to be achieved by conducting the research.⁵ They may be stated as 'general' and 'specific'.

The general objective of the research is what is to be accomplished by the research project, for example, to determine whether or not a new vaccine should be incorporated in a public health program.

The specific objectives relate to the specific research questions the investigator wants to answer through the proposed study and may be presented as primary and secondary objectives, for example, primary: To determine the degree of protection that is attributable to the new vaccine in a study population by comparing the vaccinated and unvaccinated groups.⁵ Secondary: To study the cost-effectiveness of this programme.

Young investigators are advised to resist the temptation to put too many objectives or over-ambitious objectives that cannot be adequately achieved by the implementation of the protocol.³

5. Variables: During the planning stage, it is necessary to identify the key variables of the study and their method of measurement and unit of measurement must be clearly indicated. Four types of variables are important in research:⁵

a. Independent variables: variables that are manipulated or treated in a study in order to see what effect differences in them will have on those variables proposed as being dependent on them. The different synonyms for the term 'independent variable' which are used in literature are: cause, input, predisposing factor, risk factor, determinant, antecedent, characteristic and attribute.

b. Dependent variables: variables in which changes are results of the level or amount of the independent variable or variables.

Synonyms: effect, outcome, consequence, result, condition, disease.

c. Confounding or intervening variables: variables that should be studied because they may influence or 'mix' the effect of the independent variables. For instance, in a study of the effect of measles (independent variable) on child mortality (dependent variable), the nutritional status of the child may play an intervening (confounding) role.

d. Background variables: variables that are so often of relevance in investigations of groups or populations that they should be considered for possible inclusion in the study. For example sex, age, ethnic origin, education, marital status, social status etc.

The objective of research is usually to determine the effect of changes in one or more independent variables on one or more dependent variables. For example, a study may ask "Will alcohol intake (independent variable) have an effect on development of gastric ulcer (dependent variable)?"

Certain variables may not be easy to identify. The characteristics that define these variables must be clearly identified for the purpose of the study.

6. Questions and/ or hypotheses: If you as a researcher know enough to make prediction concerning what you are studying, then the hypothesis may be formulated. A hypothesis can be defined as a tentative prediction or explanation of the relationship between two or more variables. In other words, the hypothesis translates the problem statement into a precise, unambiguous prediction of expected outcomes. Hypotheses are not meant to be haphazard guesses, but should reflect the depth of knowledge, imagination and experience of the investigator.⁵ In the process of formulating the hypotheses, all variables relevant to the study must be identified. For example: "Health education involving active participation by mothers will produce more positive changes in child feeding than health education based on lectures". Here the independent variable is types of health education and the dependent variable is changes in child feeding.

A research question poses a relationship between two or more variables but phrases the relationship as a question; a hypothesis represents a declarative statement of the relations between two or more variables.⁷

For exploratory or phenomenological research, you may not have any hypothesis (please do not confuse the hypothesis with the statistical null hypothesis).¹ Questions are relevant to normative or census type research (How many of them are there? Is there a relationship between them?). Deciding whether to use questions or hypotheses depends on factors such as the purpose of the study, the nature of the design and methodology, and the audience of the research (at times even the outlook and preference of the committee members, particularly the Chair).⁶

7. Methodology: The method section is very important because it tells your research Committee how you plan to tackle your research problem. The guiding principle for writing the Methods section is that it should contain sufficient information for the reader to determine whether the methodology is sound. Some even argue that a good proposal should contain sufficient details for another qualified researcher to implement the study.¹ Indicate the methodological steps you will take to answer every question or to test every hypothesis illustrated in the Questions/hypotheses section.⁶ It is vital that you consult a biostatistician during the planning stage of your study,⁸ to resolve the methodological issues before submitting the proposal.

This section should include:

Research design: The selection of the research strategy is the core of research design and is probably the single most important decision the investigator has to make. The choice of the strategy, whether descriptive, analytical, experimental, operational or a combination of these depend on a number of considerations,⁵ but this choice must be explained in relation to the study objectives.³

Research subjects or participants: Depending on the type of your study, the following questions should be answered^{3,5}

- What are the criteria for inclusion or selection?
- What are the criteria for exclusion?
- What is the sampling procedure you will use so as to ensure representativeness and reliability of the sample and to minimize sampling errors? The key reason for being concerned with sampling is the issue of validity-both internal and external of the study results.⁹
- Will there be use of controls in your study? Controls or comparison groups are used in scientific research in order to increase the validity of the conclusions. Control groups are necessary in all analytical epidemiological studies, in experimental studies of drug trials, in research on effects of intervention programmes and disease control measures and in many other investigations. Some descriptive studies (studies of existing data, surveys) may not require control groups.
- What are the criteria for discontinuation?

Sample size: The proposal should provide information and justification (basis on which the sample size is calculated) about sample size in the methodology section.³ A larger sample size than needed to test the research hypothesis increases the cost and duration of the study and will be unethical if it exposes human subjects to any potential unnecessary risk without additional benefit. A smaller sample size than needed can also be unethical as it exposes human subjects to risk with no benefit to scientific knowledge. Calculation of sample size has been made easy by computer software programmes, but the principles underlying the estimation should be well understood.

Interventions: If an intervention is introduced, a description must be given of the drugs or devices (proprietary names, manufacturer, chemical composition, dose, frequency of administration) if they are already commercially available. If they are in phases of experimentation or are already commercially available but used for other indications, information must be provided on available pre-clinical investigations in animals and/or results of studies already conducted in humans (in such cases, approval of the drug regulatory agency in the country is needed before the study).³

Ethical issues:³ Ethical considerations apply to all types of health research. Before the proposal is submitted to the Ethics Committee for approval, two important documents mentioned below (where appropriate) must be appended to the proposal. In addition, there is another vital issue of Conflict of Interest, wherein the researchers should furnish a statement regarding the same.

- The Informed consent form (informed decision-making): A consent form, where appropriate, must be developed and attached to the proposal. It should be written in the prospective subjects' mother tongue and in simple language which can be easily understood by the subject. The use of medical terminology should be avoided as far as possible. Special care is needed when subjects are illiterate. It should explain why the study is being done and why the subject has been asked to participate. It should describe, in sequence, what will happen in the course of the study, giving enough detail for the subject to gain a clear idea of what to expect. It should clarify whether or not the study procedures offer any benefits to the subject or to others, and explain the nature, likelihood and treatment of anticipated discomfort or adverse effects, including psychological and social risks, if any. Where relevant, a comparison with risks posed by standard drugs or treatment must be included. If the risks are unknown or a comparative risk cannot be given it should be so stated. It should indicate that the subject has the right to withdraw from the study at any time without, in any way, affecting his/her further medical care. It should assure the participant of confidentiality of the findings.
- Ethics checklist: The proposal must describe the measures that will be undertaken to ensure that the proposed research is carried out in accordance with the World Medical Association Declaration of Helsinki on Ethical Principles for Medical research involving Human Subjects.¹⁰ It must answer the following questions:
 - Is the research design adequate to provide answers to the research question? It is unethical to expose subjects to research that will have no value.
 - Is the method of selection of research subjects justified? The use of vulnerable subjects as research participants needs special justification. Vulnerable subjects include those in prison, minors and persons with mental disability. In international research it is important to mention that the population in which the study is conducted will benefit from any potential outcome of the research and the research is not being conducted solely for the benefit of some other population. Justification is needed for any inducement, financial or otherwise, for the participants to be enrolled in the study.
 - Are the interventions justified, in terms of risk/benefit ratio? Risks are not limited to physical harm. Psychological and social risks must also be considered.
 - For observations made, have measures been taken to ensure confidentiality?

Research setting:⁵ The research setting includes all the pertinent facets of the study, such as the population to be studied (sampling frame), the place and time of study.

Study instruments:^{3,5} Instruments are the tools by which the data are collected. For validated questionnaires/interview schedules, reference to published work should be given and the instrument appended to the proposal. For new a questionnaire which is being designed specifically for your study the details about preparing, precoding and pretesting of questionnaire should be furnished and the document appended to the proposal. Descriptions of other methods of observations like medical examination, laboratory tests and screening procedures is necessary- for established procedures, reference of published work cited but for new or modified procedure, an adequate description is necessary with justification for the same.

Collection of data: A short description of the protocol of data collection. For example, in a study on blood pressure measurement: time of participant arrival, rest for 5p. 10 minutes, which apparatus (standard calibrated) to be used, in which room to take measurement, measurement in sitting or lying down position, how many measurements, measurement in which arm first (whether this is going to be randomized), details of cuff and its placement, who will take the measurement. This minimizes the possibility of confusion, delays and errors.

Data analysis: The description should include the design of the analysis form, plans for processing and coding the data and the choice of the statistical method to be applied to each data. What will be the procedures for accounting for missing, unused or spurious data?

Monitoring, supervision and quality control: Detailed statement about the all logistical issues to satisfy the requirements of Good Clinical Practices (GCP), protocol procedures, responsibilities of each member of the research team, training of study investigators, steps taken to assure quality control (laboratory procedures, equipment calibration etc)

Gantt chart: A Gantt chart is an overview of tasks/proposed activities and a time frame for the same. You put weeks, days or months at one side, and the tasks at the other. You draw fat lines to indicate the period the task will be performed to give a timeline for your research study (take help of tutorial on youtube).¹¹

Significance of the study: Indicate how your research will refine, revise or extend existing knowledge in the area under investigation. How will it benefit the concerned stakeholders? What could be the larger implications of your research study?

Dissemination of the study results: How do you propose to share the findings of your study with professional peers, practitioners, participants and the funding agency?

Budget: A proposal budget with item wise/activity wise breakdown and justification for the same. Indicate how will the study be financed.

References: The proposal should end with relevant references on the subject. For web based search include the date of access for the cited website, for example: add the sentence "accessed on June 10, 2008".

Appendixes: Include the appropriate appendixes in the proposal. For example: Interview protocols, sample of informed consent forms, cover letters sent to appropriate stakeholders, official letters for permission to conduct research. Regarding original scales or questionnaires, if the instrument is copyrighted then permission in writing to reproduce the instrument from the copyright holder or proof of purchase of the instrument must be submitted.

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