

Review Article

Synopsis Writing Guidelines for Health Research Project

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A B S T R A C T

Synopsis writing is the very basic first step in a research plan. This represents a concise summary of an upcoming study that describes the purpose of the research. The construction of a synopsis should make it easier for the reviewer to understand the study work. The introduction should explain to the reader why the study was started, with a clear-cut research question, and identification of any knowledge gaps. Research work aims to provide an answer to the research question. The research question and study plan should fulfil the Feasible, Interesting, Novel, Ethical, and Relevant (FINER) criteria. A hypothesis is an idea or explanation for something that is based on known facts but has not yet been proven. A review of the literature helps to identify the existing knowledge about the concerned subjects and suggests new research topics and questions. All references quoted in the synopsis should be listed in the reference section in a standardised format for referencing.

Keywords: Hypothesis, Objective, Population, Review, Study Design, Variables

Introduction

Health research is defined as the organised collection, explanation, examination, and evaluation of data with the goal of improving the well-being of individuals. A synopsis is a concise summary of an upcoming study that describes the purpose of the research and the method of conducting research. It forms an outline of the intended work. It provides the reviewers with a comprehensive perspective of the research for quick analysis. It should be brief, yet to the point. A synopsis of a research project must be presented to an academic institution or a government agency or to the appropriate authorities for approval of the work, ethical clearance, financial assistance from funding agencies, and registration to universities for the granting of a degree. Currently, in the current BAMS curriculum, a brief terminology used in research work has been introduced

to the final year syllabus. Also, the syllabus of the 1st-year BAMS course prescribed by NCISM has included the applicability of Pramanas for research purposes. Synopsis writing is the very basic first step in the research project. After graduation, when students pursue their post-graduation, they have little idea about how to write a synopsis for further research. The synopsis is an essential component of a research project. Many institutions have made it essential for postgraduate students to write a thesis as a part of their postgraduate coursework. Very few works have been published regarding guidelines for writing a research project synopsis. In this article, a guideline has been provided for the postgraduate and PhD students for writing a health research project synopsis. The construction of a synopsis should make it easier for the reviewer to understand the study work. Every synopsis should have the contents described in Table 1.

Table I. Contents of Synopsis

- Title
- Introduction (background, state-of-the-art problem analysis, problem statement)
- Research question
- Aims and objectives
- Hypothesis
- Delimitation (lacune in existing knowledge)
- Review of literature
- Methodology (study design, sample size, inclusion criteria, exclusion criteria, duration of the study, sampling, variables, methods of data collection, and data analysis)
- Expected outcome
- Ethical considerations
- Implementation time plan
- References
- Appendix I (Research matrix)
- Appendix II (Literature search management)
- Appendix III (Data collection instruments)
- Appendix IV (Budget)

Topic Selection

What motivates the research has an impact on the topic that is chosen. Curiosity, medical requirements, financial gain, and opportunities are the driving forces behind the research. The sources from which the academician draw their ideas for research topics are varied. It's critical to be familiar with the research literature while planning, carrying out, and reporting research projects. This is true, both for determining where research gaps exist and for writing the research proposal. Whatever study topic is chosen, it must meet the standards of feasibility, interest, novelty, ethics, and relevance (FINER criteria).

Following the selection of what to study, it is necessary to plan the research strategy. Planning the research strategy never wastes time. A good research topic should appropriately summarise the paper's contents. It should not be excessively lengthy or too brief; it should normally contain 10–12 words. Some publications, but not all, accept sub-titles. The title of the paper should not contain any irrelevant terms or expressions such as "Observations on" or "A study of". The title and abstract should not contain abbreviations. Any name of the institution and the number of cases to be studied should not be included.

What Should be Included in the Synopsis Part of the Introduction?

The introduction provides a brief overview of the research question. It starts by formulating an accurate and brief problem description that identifies the predictor and outcome variables. The introduction should describe why the study was initiated, include a specific research topic, and indicate any knowledge gaps. It should be created with a specific question in mind to attract the reader's curiosity.

This review is intended to demonstrate not just the candidate's good and up-to-date understanding of the subject, but additionally, his or her intellectual abilities. It should only contain material relevant to the work done and not the information found in textbooks. It should show the candidate's ability to create and gather information from various sources. Most of the claims made in the introduction should be supported by additional research in the field that demonstrates the significance of the question, for example, a previous study may be cited that mentioned the problem as an area where further research needs to be done. It must appropriately credit the contributions of earlier researchers and provide citations that support them.

Preferred Words

The following word groups should be preferred while writing the research proposal, whenever possible.

Abstract nouns are better replaced with verbs, for example, change "Measurements were performed on the central tendency" to "The central tendency was measured" or "We measured the central tendency"; replace "The analysis of the statistical findings was made" with "Statistical findings were analysed" or "We analysed the statistical findings".

- **Compound Nouns:** Noun clusters, (e.g., patient gonadotropic hormone level (the level of gonadotropic hormone in patients)) and abbreviations should be avoided in the title.
- **Sexist Words:** Try to replace words like mankind, manpower, policeman, and foreman.
- **Dehumanising Words:** Patients or volunteers should be used instead of referring to individuals as cases or subjects. Males and females are more appropriate for animal terminology, while men and women are better for humans.

- **Slang Words and Jargons:** These words have arbitrary meanings and should not be used for writing research papers.

In general, the introduction section should be written in the present tense, and the methodology section should be in the simple future tense.

Research Question

Research work aims to provide an answer to the research question. Finding the solution ought to benefit our level of understanding. Additionally, it must meet the FINER criteria. Using the PICOT structure, which stands for Population, Intervention, Comparison, and Outcome, is a useful method for condensing research questions that examine the impact of therapy. Objectives of the study and research questions are nearly identical – with the difference occurring from sentence vs question structure. The research question is the objective of the study and the ambiguity the investigator wants to resolve.

The research question should fall into either a descriptive or an analytical category. Descriptive questions involve observations to measure the quantity; it could be weight, knowledge, or to what extent a problem exists in the community. There are no comparison groups or interventions in a descriptive research question, e.g., “Is BMI associated with gender?”. An analytical question involves comparison groups, which could be an intervention or an experiment to test a hypothesis, e.g., whether quick walking by obese persons for at least 45 minutes daily reduces BMI levels as compared to those who do not. A good research question should identify the population being examined as well as the relevant predictor and outcome. The typical form of a research question is “Is X associated with Y in population Z?” or (for a clinical trial), “Does X cause Y in population Z?”.

This general research question must be narrowed down to a specific research question which involves breaking the research question into smaller, simpler elements and selecting one or two among them to establish the protocol. The six question words may be thought of to help narrow it down: who, what, where, when, why, and how.

Consider, for example, the general research question: Should people eat more red meat?

The specific questions can be:

How often do Indians eat red meat?

Does eating more red meat increase the risk of cardiovascular disease?

Does eating more red meat increase the risk of type 2 diabetes or CHD among people with sedentary lifestyles?

A good research topic, a good research question, and a good study plan should satisfy the FINER criteria. The FINER criteria have been given in Table 2.

Objective

Specific objectives are statements of the research question(s). One should include at least one overall objective describing the project’s contribution to one’s field. After that, two or three precise goals should be listed that the project would try to achieve. Typically, the overarching goal has little to do with solving a particular issue or providing a specific response. Instead, it explains how being concise would advance the field to achieve the requisite aims. To assist in achieving goals, objectives should meet the SMART criteria (Specific, Measurable, Achievable, Realistic, and Timed). Use of the words like “Study”, and “To Study” is not recommended in the objectives at all. To study is a very poor statement of objective and it should be avoided.

Table 2. FINER Criteria for a Good Research Question and Study Plan

Feasible	Adequate number of subjects, appropriate study design, skills in technology, inexpensive in terms of both time and money and fundable Optimises human and technical resources
Interesting	The investigator and the rest of the team should be fascinated by the possibility of finding the solution.
Novel	The study should provide new findings. The study should confirm, refute, or extend previous findings. This may result in changes in research methodology, ideas of wellness and illness, and medical practice.
Ethical	The study should be approved by the institutional ethics board.
Relevant	The study should generate new scientific knowledge, clinical practice, or health policy. It may provide directions for future research.

Table 3. Examples of Good and Bad Study Objectives

S. No.	Bad Objectives	Good Objectives
1.	Determine the importance of physical activity among obese individuals.	Estimate the prevalence of physical activity among obese individuals.
2.	Assess physical activity and reduction in BMI.	Estimate the effect of physical activity on BMI among obese individuals.
3.	Evaluate depression and obesity.	Determine whether depression is more common among obese as compared to non-obese individuals.

Translating Research Questions to Objectives

A research question should be translated to objective(s) by using appropriate verbs based on the study design and appropriate epidemiological terms. Based on the types of study, in descriptive studies, we estimate a quantity. So, the verb “estimate” should be used, e.g., estimate the prevalence of mental health among unemployed individuals. In analytical studies, a hypothesis is tested. So, the verb “determine” should be used, e.g., determine whether exercise for at least one hour daily among obese individuals results in decreased blood cholesterol level by 10% as compared to those who do not.

It is advisable to divide the objectives into primary and secondary objectives because the statement of objectives needs to be very clear about the research issue it is seeking to address, for example, “Does an outdoor physical regime enhance the mental well-being among adults suffering from severe depression?”. A research question is converted into an objective as “Estimate the effect of an outdoor physical exercise regime on the mental well-being status of people with clinical depression”. Some examples of good and bad objectives are mentioned in Table 3.

Research Hypothesis

A hypothesis is a speculation, prediction or interpretation of a connection between two or more variables. A good hypothesis must be based on an appropriate research question and should be easy to understand (one exposure and one outcome), specific (no ambiguity regarding the study, participants, or variables), and stated in advance (written at the outset and focused on the primary objective). A hypothesis is an idea or explanation for something that is based on known facts but has not yet been proven. The key components of the study are described in the investigator’s statement, including the population of interest, the predictor and outcome variables, and an anticipated result.

The hypothesis could be simple or complex. A simple hypothesis has a single predictor and a single outcome

variable, e.g., “Among obese individuals, a sedentary lifestyle is linked with an enhanced risk of developing diabetes”. A complex hypothesis has more than one predictor variable, e.g., “Among obese individuals, a sedentary lifestyle and alcohol consumption is linked with an enhanced risk of developing diabetes”. In this example, a sedentary lifestyle and alcohol consumption are two predictor variables and increased risk of developing diabetes is the outcome variable. A complex hypothesis may also have more than one outcome variable, e.g., “Among obese individuals, a sedentary lifestyle is linked with an enhanced risk of developing diabetes and heart disease”. In this example, a sedentary lifestyle is a predictor variable, and diabetes and heart disease are outcome variables.

Other Examples of Research Hypothesis

- a) The research hypothesis was that migraine headaches would be associated with at least a 15% increase in the risk of stroke.
- b) Students who sleep at least 8 hours per night on average achieve higher grades in standardised tests than students who sleep less than 8 hours per night.

Null Hypothesis

At a simple level, the null hypothesis is the counterproposal to the original hypothesis. The null hypothesis proposes that no statistical significance exists in a set of given observations and that any differences are due to chance (sampling error) alone, for example, if the research question is “Does taking aspirin every day reduce the chance of having a heart attack?”, the null hypothesis for this is “Taking aspirin daily does not affect the risk of heart attack”.

Literature Review

A literature review is an important step in every health research project because it serves as a bridge between what is known and what is unknown.

A literature review helps to identify the existing knowledge about the concerned subjects and suggests new research topics and questions. By reading the existing articles, we

may find certain lacunae in the existing language, which makes us carry out new research and aid in developing new research questions. This is an information-seeking process. Information should be obtained from valid resources on existing subjects by critical appraisal method. The valid resources may be manual or computerised methods to identify a set of potentially useful articles. The information can also be retrieved from textbooks, manuscripts, published articles, or conference proceedings. A set of queries can be gathered with the help of computer-assisted searches from databases like MEDLINE and MEDLARS, PubMed, Google Scholar, and DHARA, and from direct communications with other researchers. Searching a database can be done using the Boolean query method "AND, OR, NOT". An enormous amount of information may be found online. It is important to analyse only the relevant data. The process of the review of literature is now quite easy because of information technology.

It achieves the following:

- It explains the advances that other academicians have achieved in the area when addressing similar problems. Then, the proposed research project should be differentiated from previous efforts to demonstrate that something new is being made in the field.²
- It offers a methodical investigation procedure that can be used to expand or improve our knowledge on a particular topic of interest.

Narrative reviews along with systematic reviews are the two sorts of reviews.¹⁷ A narrative review is typically produced by subject-area experts. The studies evaluated in a narrative review are not discovered or evaluated in a systematic, standardised, and objective manner. Experts typically write reviews to provide an update on a specific subject. A systematic review contains an explicit statement of objectives with a spelled-out research question. The publication's data sources (including grey literature) and technique of selection are described. The review is carried out in compliance with an easily

understood and reproducible strategy. A systematic review is often conducted more effectively by non-experts on the topic, who are experts in writing reviews of systematic literature. Meta-analysis is a special type of systematic review. When the entire literature review is summarised, it should clearly summarise the current understanding of the subject and research question.

Material and Methods

The general layout of the study is detailed in the methodology section. In this section, the complete detailed plan of how the study would be conducted is mentioned. This section covers all areas starting from the study design and including a description of the interventions, study population, operational definitions and the sampling method, in case of an experimental study.

It describes how was the sample size calculated and what would be the data collection methods. It explains what tools were used for data collection and the analysis plan. Details on the study setting should be included, along with the tools and resources that one has at one's disposal to conduct the research.

Study Design

More than one study design may be used to answer a research question. The researcher must select the appropriate design for the specific study. Every study design has a place and positive and negative aspects. However, not all types of designs are always feasible for a specific study. The two basic types of research designs are observational and experimental or intervention. The researchers participating in an observational study are kept away from the events taking place in the study. They simply observe and document the data. In experimental or interventional research, the investigators add an intervention and examine the events that occur during the research. Morbidity indicators are calculated by choosing an appropriate study design. The different types of study designs¹⁸ are shown in Figure 1.

Table 4. Types of Study Designs and Morbidity Indicators

NATURE OF OBJECTIVE			
Describe 1 group		Compare 2 groups	
Acute	Chronic	Frequent	Rare
Cohort/Surveillance	Cross-sectional/Cohort	Cohort/Cross-sectional analytical	Case-Control (Acute-prospective Chronic-Retrospective)
Incidence	Prevalence	Relative Risk/Odds ratio	Odds Ratio

Study Samples

- **Target Population:** The target population is defined by clinical and demographic characteristics as the large set of people throughout the world to which the results may be generalised. The target population has to represent an entire subset of the population that is of interest; individuals of the target population must also be specified by the boundaries of the population of interest,¹⁹ e.g., teenagers with bronchitis.
- **Accessible Population:** The accessible population is a geographically and statistically defined subset of the target population available for research, for example, adolescents with pneumonia residing in Mumbai in the current year.
- **Intended Study Sample:** A portion of the accessible population that the researcher hopes to involve in the research project is known as the intended study sample.
- **Actual Study Sample:** The actual study sample is the group of contributors that take part in the research project.

Variables

A variable in the field of statistics is defined as the characteristics of a study objective. These are elements that can vary. These modifications may have an impact on the outcome of the research. As a result, it is critical to determine the variables at the beginning of the planning process. They should be quantified using a convenient unit. Understanding the numerous variables in a research study helps refine the objectives.

- **Quantitative vs Qualitative:** A variable can gather either qualitative or quantitative information. A variable that differs in number is referred to as a quantitative variable (for example, the weight of a group of participants), but a variable that differs in terms of quality is referred to as a qualitative variable (for example, the Prakriti type).
- **Quantitative Variables (Discrete or Continuous):** Discrete variables are variables that count the number of individual items or values (e.g., the number of obese patients in a hospital). Continuous variables can give measurements of continuous or non-finite values. These take any value among the two expected values (e.g., distance, volume, and age).
- **Qualitative Variables (Categorical and Ordinal):** Categorical variables, as the name implies, are variables that may be classified into different groups (for instance, race or the kind of disease). Ordinal variables, also known as ranking variables, are similar to categorical variables in that they can be ordered (for example, a scale for the level of mental well-being). A variable has the ability to represent multiple

types. If the scale is numerical and does not need to be maintained as discrete integers, an ordinal variable can also be utilised as a quantitative variable, for example, star ratings on product reviews are ordinal (1 to 5 stars), while the average star rating is quantitative.

Predictor and Outcome Variables

In the context of an experimental study, predictor variables are the variables that can be manipulated by the researcher in order to influence the outcome of the study, for example, the SCORAD (Scoring Atopic Dermatitis) could be one outcome variable in a dermatitis clinical trial. The predictor variable is one that doesn't get affected by the experiment but can be changed to influence the outcome variable.²⁰ Predictors are sometimes termed independent variables and outcomes dependent variables, but the meaning of these terms is less self-evident, and we prefer to avoid their use.²¹ Confounders are variables which can have an effect on the experiment. A confounding variable is an undetected third variable that affects both the suspected cause and the supposedly occurring effect. They are linked with dependent and independent variables and can cause false associations. Confounding variables run a high risk of introducing a variety of research biases to the work, for example, an investigator wants to see a relationship between a manual worker working in an asbestos factory and lung cancer. Manual workers have a habit of smoking so in this case, smoking is a confounder associated with lung cancer.

Importance of Study Design and Appropriate Sample Size

The appropriate sample size can be easily determined using digital statistical programmes, but researchers must understand the concepts that support the calculation as well as the boundaries. The statistical principle underlying the estimation of the appropriate sample size is easy. When we investigate an appropriate sample, the aim is to generalise the results to the population from where the sample was derived. The sampling error cannot be reduced to zero unless we study the entire population. Analytical statistics can assist us in defining the possibility that a finding difference or a relationship can be generalised to the population from which the sample was obtained.²² This is referred to as the statistical significance of the discovery. The sample size is an important factor in calculating statistically probable outcomes. The smaller the sample size, the less probable it is that the findings can be generalised.

- It is not always evident that the larger the sample size, the better the study. An increase in sample size will not help the study after a certain point. The large scale of the study may have the opposite outcome, lowering the quality of measurement or obtaining

information. It is also preferable to ensure that the sample is representative rather than overly huge.

- The study design should include the complete target population. An inappropriate study design causes a systematic error (type II error). In this situation, the investigator fails to reject a null hypothesis that is actually false in the population. If the appropriate sample size is not calculated, then the random error (type I error) occurs. The researcher rejects a null hypothesis that is actually true in the study population. Research can never be free of errors, but errors can be predicted and minimised. They can be minimised by increasing sample size and precision.

The following are the prerequisites for calculating sample size²³:

1. Type I error, sampling error, or p value.
2. Type II error or non-sampling error.
3. Sample estimates of mean, SD, percentage etc.

Ethical Considerations

Ethical committee approval from the research organisation is essential in all human and animal investigations, and a verification document must be presented. Human research (or studies involving human biological materials) requires approval from a governmental, institutional, or analogous ethics committee, as well as a national ethics committee.

References Format

MLA style, developed by the Modern Language Association; APA style, governed by the Publication Manual of the American Psychological Association; CMS footnote style, developed by the Council of Biology Editors; and CBE number style, developed by the Council of Biology Editors are some of the various referencing formats. There are computerised referencing systems that are available freely for easy management of references e.g., Mendeley, Endnote, Zotero, etc.

Conflicts of Interest: There are no conflicts of interest.

References

1. World Health Organization. Health research methodology: a guide for training in research methods. 2nd ed. World Health Organization; 2001. p. 1-2.
2. Betkerur J. Guidelines for writing a research project synopsis or protocol. Indian J Dermatol Venereol Leprol. 2008;74(6):687-90. [PubMed] [Google Scholar]
3. Fathalla MF. A practical guide for health researchers. World Health Organization; 2004. p. 39-41.
4. Fathalla MF. A practical guide for health researchers. World Health Organization; 2004. 131 p.
5. Fathalla MF. A practical guide for health researchers. World Health Organization; 2004. p. 80-1.
6. Fathalla MF. A practical guide for health researchers. World Health Organization; 2004. p. 142-4.
7. Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. Designing clinical research. 4th ed. Lippincott Williams & Wilkins; 2013. p. 17-8.
8. Eldawlatly A, Alshehri H, Alqahtani A, Ahmad A, Al-Dammas F, Marzouk A. Appearance of population, intervention, comparison, and outcome as research question in the title of articles of three different anesthesia journals: a pilot study. Saudi J Anaesth. 2018 Apr-Jun;12(2):283-6. [PubMed] [Google Scholar]
9. Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. Designing clinical research. 4th ed. Lippincott Williams & Wilkins; 2013. 16 p.
10. Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. Designing clinical research. 4th ed. Lippincott Williams & Wilkins; 2013. p. 17-9.
11. Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. Designing clinical research. 4th ed. Lippincott Williams & Wilkins; 2013. p. 2-3.
12. Ponnaiah M. Formulating research question, hypothesis, and objectives. Health research fundamental. Chennai: ICMR - National Institute of Epidemiology; 2019. p. 23-5.
13. Ponnaiah M. Formulating research question, hypothesis, and objectives. Health research fundamental. Chennai: ICMR - National Institute of Epidemiology; 2019. p. 35-6.
14. Fathalla MF. A practical guide for health researchers. World Health Organization; 2004. 220 p.
15. Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. Designing clinical research. 4th ed. Lippincott Williams & Wilkins; 2013. p. 44-7.
16. Swayam [Internet]. Health research fundamental; 2019 [cited 2023 May 10]. Available from: https://onlinecourses.nptel.ac.in/noc19_ge24/preview
17. Fathalla MF. A practical guide for health researchers. World Health Organization; 2004. p. 145-6.
18. Mehendale S. Study plan and project management. Health Research Fundamental. Chennai: ICMR - National Institute of Epidemiology; 2019. p. 240-1.
19. Willie MM. Differentiating between population and target population in research studies. Int J Med Sci Clin Res Stud. 2022;2(6):521-3. [Google Scholar]
20. Kaliyadan F, Kulkarni V. Types of variables, descriptive statistics, and sample size. Indian Dermatol Online J.

- 2019 Jan-Feb;10(1):82-6. [PubMed] [Google Scholar]
21. Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. *Designing clinical research*. 4th ed. Lippincott Williams & Wilkins; 2013. p. 17-22.
 22. Fathalla MF. *A practical guide for health researchers*. World Health Organization; 2004. p. 52-4.
 23. Syamalan K. *Statistics in medicine*. 2nd ed. Thiruvananthapuram: Global Education Bureau; 2012. p. 240-3.