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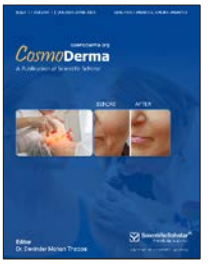

Resident Forum

Steps in writing a research protocol for thesis

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INTRODUCTION

Research is an integral part and an important domain of the postgraduate curriculum. The research proposal is a written document proposing a research project in a summarised manner. The question raised in the mind of the researcher at the time of writing a research protocol are "*what are the elements of the research proposal*," "*what is study problem and rationale, research question and hypothesis*," "*what are the aims and objectives of the study*," and "*what are study variables and what is study design*."[1] If answers to these questions are known, then writing the research proposal can be done with confidence.

During postgraduation, the research protocol writing is required for various purposes such as Institutional Scientific Committee approval, Ethical Committee approval, Animal Ethics Committee approval, for obtaining funds, and for collaboration approval. These committees need a written document to know the problem or issue with a justification of proposed research, the method and novelty of the research, required expenditure, manpower and infrastructure, and the probable benefits and hazards of the research. The components of the research proposal are listed in [Flowchart 1].[1]

ELEMENTS OF RESEARCH PROTOCOL

The title of the research should be informative and interesting. It should be precise, clear, and appropriate. It should reflect the setting or design of the study.[2]

Background (review of literature): It is a summary of relevant knowledge from the available literature. It should support the question, "*How you have thought for the present study?*" The review of literature should be well organized, thorough, and complete, relevant up to date, and logical. It should build the need for the present study, indicate gaps in the existing knowledge, stick to the objective of the study, and be cited with original sources.[1,3,4]

Problem statement: The study problem indicates the concerned issues about the health, disease, society, or system. The research problem should be relevant, clear, and logically supported.

Rationale: It is a set of reasons or logical basis of the research study. It is an argument in favor of the implementation of the proposed study. It offers reasons for proceeding to approach the problem with a particular method. The rationale should contain the following facts: "*Why the research is required* (reason)*?*" "*What research is required* (objective)*?*" "*What results are expected* (result)*?*" "*How it will benefit society, patient or science* (benefits)*?*" *The rationale* should support positively the above-mentioned facts and should help to fill the gap in the existing knowledge.[5]

Flowchart 1: Steps for writing a scientific article.

Novelty: It states the quality of the research study being novel, new, or unique. It refers to one or elements that are new in the research, including new methodology or new observation. Do not exaggerate the novelty mentioning that "it is first study in the world" or so on.[1]

Research question: It is uncertainty about a problem that can be challenged, examined, and analyzed. It specifies the focus of the study or what is tried to be answered during the study. The research question should meet the FINER criteria that include a feasible, interesting, novel, ethical, and relevant.[1] The PICOT (*population of interest, interventions, control, outcomes of interest, and time frame*) format is a strategy for framing a research question.[1] The research question can be expanded by including additional variables such as demographics (gender, age, and so on), demographic location, socioeconomic status, specificity of condition, and duration. Do not state the implications of the study in the research question. The research question can have a variable list. The research question should be answerable with the help of aims and objectives.[6,7]

Hypothesis: It is a statement about the outcome of the research. It is a prediction that provides an explanation for an observed event. Research hypothesis can be written only if the study has the research question and it is applicable only if there is a measurable result or condition. The hypothesis should be proven correct or incorrect.[7]

Research aim: It is defined as a broad goal or over-reaching purpose of a research project. The aim is not very specific. It is an achievable goal over an issue.

Research objectives: These are statements that are highly specific, focused, and measurable. There may be one or more research objectives. Objectives are required to avoid the collection of unnecessary data, which are not strictly required to solve the research problem The following words can be used for writing objectives: "*to find, to assess, to identify, to determine, to compare, to calculate, to describe, to analyze, to establish* and so on."[7]

The research objectives should follow 'SMART' protocol: S: specific, M: measurable, A: attainable, R: realistic, T: time-bound. It should be RFLOUM: R: relevant, F: feasible, L: logical, O: observable, U: unequivocal, M: measurable. Objectives should help to fulfill the aim of the study.

Types of objectives:

- *Primary objective*: It indicates the exact origin of the study and it depends on one or more variable that is derived from the existing lacunae in the literature. Calculation of the sample size mostly depend on the primary objective. It should include investigational setup and variable.[1]
- *Secondary objectives*: These are additional objectives that can be studied in the due course of time and in the same setup.[1]

Review of literature: It is essential to initiate the research. It is performed for the following purposes: To find the existing knowledge, to avoid the repetition of the study, to decide the sample size, to find the gap in the existing knowledge, to decide the desirable material and methods, to find earlier confounding factors so that same can be avoided, and so on. It is advised to do the extensive review before submitting the protocol for the approvals. The keywords play an important role in review searches on the internet. Use widely accepted search engines such as PubMed, Scopus, and Google.[1]

Research methods: It provides the information of a clear and precise description of how the study will be performed. It describes the experimental setting, required materials, list of variables, study design, sampling method, data collection, and analysis method.

***Study variables*:** These are defined as a component that varies in quality or quantity. Variables may be dependent, independent, or confounding variables. The dependent variable is the effect that will be studied and it is a measurable outcome of the study. The independent variable is the core of an experimental study. It can be isolated and manipulated by the researcher.

Table 1: Study designs.

A. Quantitative
   1. Descriptive studies (Objective of the study is to describe the variable)
      a. Correlational studies (Nonexperimental research method which studies the relationship between two variables)
      b. Case reports (A detailed report of the diagnosis, treatment, and follow-up of an individual patient)
      c. Cross-sectional surveys (Determination of outcome at some time after exposure)
   2. Analytical studies (Objective of the study is to quantify the relationship between variables)
      a. Case-control (Determination of outcome before the exposure was determined)
      b. Cohort (Determination of outcome, sometimes after the exposure)
   3. Intervention studies (used to determine the effectiveness of an intervention)
      a. True experiment
         i. Pre-test–post-test
         ii. Factorial design
         iii. Repeated measures
         iv. Randomized control trial (Interventional study with random allocation of intervention)
      b. Quasi-experimental
         i. One group pre-test–post-test
         ii. Nonequivalent control group
         iii. Time-series

B. Qualitative: Case study, interviewing, narrative, life history, oral history, field research, and interpretive research

Confounding variables are extraneous variables that interfere with the dependent or independent variables.[8]

***Study design*:** It is a set of methods or procedures used for collecting and analyzing variables. The study designs may be quantitative or qualitative [Table 1].[1]

***Subject or sample*:** The research participants are subjects who got selected for experimental studies by the researcher. The rights of human participants depend on the constitutional laws. The basic rights of participants should be followed that includes proper respect, should be informed, should give written consent, right of privacy of the collected information, to know benefits and demerits of all possible interventions, right to exit the study at any time, right to refuse for the intervention or experimental procedure, to receive all other treatment benefits if he/she refuses participation, should gain the economic benefits against the loss in terms of journey tickets. The participants should not receive any economic benefits just for their participation.

Sample size calculation should be included in material and methods. The reference parameter and reference study utilized for the sample size calculation need to be included. The research proposal should include–exclusion criteria to reduce the effect of confounding factors or research outcomes.[1] The inclusion criteria are based on the similarity of the properties of the target population such as type and stage of disease, the subject's previous treatment history, age, sex, race, ethnicity, and so on. Exclusion criteria concern properties of population to be excluded from the current study sample based on either ethical reasons or practical issues or the factors that may lead to biases in the study's results.[1] The sample size for any study depends on the acceptable level of significance, power of the study, expected effect size, underlying event rate in the population, and standard deviation in the population.[9]

A *sampling method* is a procedure for selecting the sample (participants) that represents the entire population at a given period. The sampling saves the resources and gives results applicable to the population. There may be probability or nonprobability sampling. In probability sampling, each element in the population has an equal, independent chance of being selected. In nonprobability sampling, some elements of the population have no chance of selection or the probability of the selection.[10]

In *random allocation,* the selected participant is allocated to study the group on a chance basis. In random allocation, every member of the population has an equal chance of being selected. It helps to maximize the probability that will be comparable. Methods of randomization are drawn from a random number table and are computer-generated. Selection of cases on alternate days or selection of alternate cases is not the method of randomization.[11]

***Data collection*:** The detailed data collection sheet should include all variables, their measurement units, methods of data collection, and so on. It may include questionnaires for data collection if any.

***Data analysis*:** Research proposal should contain the data analysis procedure. Data analysis mainly depends on the type of data, such as descriptive or analytical data. The

descriptive data are expressed as shape, tendency, variability, mean, median, range, and proportion, For analytical data, the association of two or more variables and the strength of association can be assessed. This section should include the list of tests of statistical analysis of the variables and values of inferences. The value of inference includes mean, median, mode, standard deviation, coefficient of variation, degree of freedom, risk, odds ratio, sensitivity, and specificity. The use of the statistical test depends on the sample size and distribution of data, study design, and type of analysis. It should be mentioned at what *P*-value the level of significance is considered.[1,12]

Ethical considerations: All the research proposals should get through the Institutional Ethics Committee. It mainly focuses on the autonomy and protection of the participant, benefit and risk ratio, the scientific validity of the study, and informed consent. "Legally, children are not able to give informed consent until they turn 18 years." Before participation in a clinical trial, children are asked for their assent, that is, they should agree to take part. The researcher needs to explain the trial to a child in a language they can understand. As per the ICMR guidelines for children between 7 and 12 years of age, oral assent must be obtained in the presence of the parent/legally acceptable representative. For children between 13 and 18 years of age, written assent must be obtained. If a child turns 13 during the course of the study, then written assent must be obtained." The level of risk should be mentioned. ICMR classified the risk to the participants into four categories less than minimal risk, minimal risk, low risk, and more than minimal risk. [13]

Consent forms: It is a written document that provides the relevant information about the ongoing research to the participant. It should explain a clear role, risk benefits to the participant and should be signed by the participant in front of the witness. If the participant is a minor in age, then the consent form should be signed by his/her parent or legal guardian. The consent form should be in the simple and local language, contain the purpose of the study, and the procedure in brief. It should convey a clear message about "*why is this study being done,*" "*what is involved in this study and how long will it take?.*" It should include information about compensation for participation and confidentiality and should mention the right to leave the study at any time.[15]

Budget: It may be submitted for obtaining a grant. It is a financial proposal that reflects the proposed research. The budget should reflect expenditure toward the personnel (manpower), equipment, travel, overhead charges (for maintenance of institutional infrastructure, telephone, electricity, and equipment). Justification for budget includes proper justification for each segment. While preparing a budget, the yearly increasing costs of the consumable and nonconsumable items should be kept in mind. An intramural grant is a fund provided by the parent institute to faculties to support research and professional development. An extramural grant is a fund provided by external funding agencies for research.[15]

Registration of clinical trial: The principal investigator has to register all the clinical trials in India at Clinical Trial Registry–India (CTRI) on www.ctri.nic.in before enrolment of the first participant. It is a free and online public record system and is maintained to ensure transparency, accountability, and accessibility of clinical trials.[16]

References: Citation of existing knowledge is an important component of scientific writing. Vancouver format of referencing is widely accepted. Other reference stylings include Hayward referencing style, American Psychological Association System, and so on. Microsoft office has an inbuilt reference manager which is a very useful tool. Online reference managers are also available such as "zotero.org," "https://flowcite.com/reference-manager/" and so on.[17]

CONCLUSION

Qualities of good research proposal: It should provide sufficient, brief information, has a solid background, clear research question, proper study design, appropriate rationale, suitable and feasible methods, appropriate and adequate sample size, ethically acceptable, financially feasible, and is completed in feasible duration.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Nil.

Conflict of interest

There are no conflicts of interest.

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