

A Beginner's guide to research - Part I

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The dictionary defines research as 'asking questions with the goal of obtaining knowledge'^[1]. Didn't we all do that when we were children, incessantly asking questions in order to understand the how, why and what of things around us? But none of us were called 'researchers'! Somewhere down the line, our basic school education helped answer most of the questions, quenched our thirst for knowledge and we stopped being curious of the world we live in.

However, at the level of professional education especially in the field of medicine we have a quest, a quest to learn more, to look beyond what is written and to contribute a little to the field we plan to dedicate our lives to. As a beginner, one is usually unsure of how exactly to go about research. This article aims at giving a brief overview of the general methodology of conducting a research project.

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Research is not something one can begin impulsively. It is something which requires prior planning

as well as dedication and persistent working for effective execution and completion of the project. Here's a step-by-step process that one can go through while conducting research:

1. Plan and prioritize

Before undertaking a research project, one should be clear about the time, effort and finance one is ready to invest in it. It is also important to get one's resources [access to a computer, internet, literature and finances] in place.

2. Choose a topic

To choose a topic one must formulate a valid research question, which can be described by the FINER criteria^[2]:

- *Feasibility* [adequate subjects, technical expertise, time and money, scope]
- *Interesting to the investigator*
- *Novel* [confirms or refutes previous findings, provides new findings]
- *Ethical*
- *Relevant* [to scientific knowledge, clinical and health policy, future research directions]

A well-crafted research question can help one to design a study properly so as to arrive at a precise conclusion.

How can you arrive at a topic?

- a) Be alert to new ideas- have a prepared mind.
- b) Do a systematic and assiduous search, draw inspiration from other researchers; exploit similar ideas, rather than novel ones. You can also repeat or reproduce what someone else has done. For example, one can challenge the hypothesis of certain studies or check if the study is true for a population of a different ethnicity. A topic which has been studied on a small scale can be studied again on a

- c) larger study group or with a longer duration of follow up.
- c) Study the same topic sometime later, especially for efficacy of drugs. For example, one can study whether an antimicrobial drug, with previously proven efficacy, is still efficacious against a particular micro-organism after a certain period of time.
- d) Challenge existing dogmas
- e) Identify an area of importance in your country. One can study endemic diseases in one's country. The prevalence of infectious diseases is different in different countries, e.g. in South East Asia, India is the only nation reporting cases of Poliomyelitis.^[7] Also many chronic ailments show racial differences e.g. cancer of the stomach is very common in Japan but not in the United States of America.^[8]
- f) Dream- Keep the imagination roaming. It helps to be observant of your surroundings and keep an open mind; everyone knew that all objects fall downwards but only Isaac Newton discovered and defined gravity!

3. Choosing a Research Guide

It is a good idea for a student to do the first project under the guidance of a faculty member, who has prior research experience and is willing to invest adequate time for the project. Alternately, students could also assist a faculty member in an ongoing research project to get "hands-on" experience.

4. Conduct literature search

Once the topic is chosen, it is extremely important to conduct a literature search relevant to one's topic.^[3] A literature search can be done on the Internet. Some common databases are Index Medicus/MEDLINE, Web of Science, EMBASE, CAB, Cochrane, etc - these provide information and research services in areas of biomedicine, healthcare and related topics. In layman's terms, these are databases dedicated only to topics

related to medicine, healthcare and allied subjects, are indexed, and can be searched using their own interfaces such as Entrez PubMed for PubMed or even through the general search engines such as Google. One can also look through scientific journals.

5. *Design a protocol*

The protocol is the formal record of how the trial must be conducted and must be clear and detailed.^[4] Protocol is the most important document as it enlists the rationale, objectives and methodology (including planned statistical analysis) of the research study. A well-designed protocol that does not leave any room for ambiguity or multiple interpretations is likely to answer the research question. It describes the processes involved in great detail so that these are carried out uniformly and with consistency. A summary of protocol should also be provided so as to help the "non-experts" in the subject (in funding organizations and Review Boards) understand the rationale of the study.

The actual protocol

A protocol is the outline of the manner in which one intends to conduct the research. It usually comprises of the title, an introduction, aims and objectives, material and methods (including statistical analysis plan, ethics, data handling and archiving) and probable implications of the study.

- a) The title of the study should be clear and concise and indicate the nature and objective of the study.^[5]
- b) The introduction should give information about what is already known and provide justification for doing the study. It should summarize the relevant literature and clearly indicate the purpose of the study.
- c) The aims and objectives should be precise and depicted point-wise. It is better to have a limited number of manageable objectives.
- d) The material and methods should be well described and thorough such that every member of the research team knows his/ her role and how to execute various steps in the protocol.
- e) The implications of the study should indicate the outcome one expects and also how and whom the result of the study will benefit or be of use.^[3]

6. *Other relevant documents*

Apart from the protocol, one requires a patient information sheet, an informed consent form and a Case Proforma/Case Record Form.

The patient information sheet intends to inform the prospec-

tive research subject regarding the purpose and nature of the study, role of the study subject, possible benefits and risks involved, data handling and confidentiality, consequences of refusal, his/ her rights and duties and care and compensation in case of a study-related injury, amongst other issues. As it is intended to provide information to study subjects, this document should be written in a language that a layperson can understand and it should be devoid of any medical jargon. The document should also provide information about what to do in case the subject suffers from an adverse event or wishes to have additional information or clarifications related to the study.

The informed consent form is required to obtain written, informed consent from the prospective participant. It should be designed in a manner that conforms to the principles laid down under the Declaration of Helsinki.^[6]

The case proforma is the document used to record the data collected during the study.

The Institutional Ethics Committees/ Review Boards study and scrutinize all the documents referred to above. In addition, if any publicity material is to be used for inviting individuals to participate in the study, such material (advertisements, posters, brochures, etc.) also needs to be submitted to the EC/ IRB for review and clearance.

7. *Apply to the Institutional Ethics Committee*

Depending upon the nature of the study, it is mandatory to apply either to the Institutional Animal Ethics Committee or Ethics Committee for Research in Human Subjects. The services of Independent Ethics committees can also be used for larger projects and for conducting research in institutions that do not have institutional Ethics Committees or Review Boards. Once the clearance from the EC is obtained, you can commence your work and begin the journey that is challenging, exciting and enjoyable.

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