

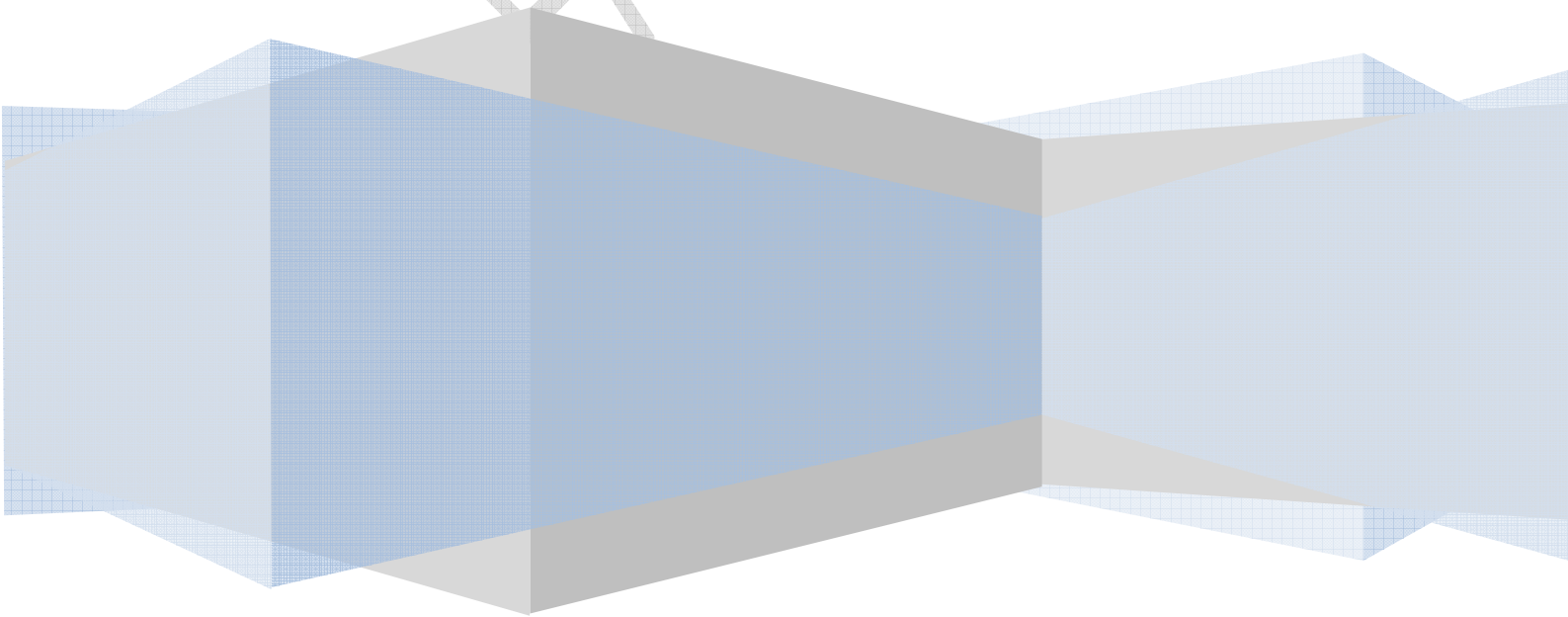
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## **Basics of research series for medical students and board candidates**

**How to do a biomedical research and how to write it?**

Dr.fahmi khan



## **How to do a biomedical research and how to write it**

Biomedical research is the broad area of science that involves the investigation of the biological process and the causes of disease through careful experimentation, observation, laboratory work, analysis, and testing. Scientists expand this knowledge base to discover ways to prevent ill-health, and to develop beneficial products, medications, and procedures to treat and cure diseases and conditions that cause illness and death in our-selves, our families and friends, our pets, farm animals, and wildlife. As a consultant in my department I have been asked several times by my colleagues, how to do a research? If you are attempting to do a research project, the steps below will help you to complete your project:

- 1. Choose the area of research**
- 2. Choose a topic which interests and challenges you**
- 3. Formulate a research question**
- 4. Critically review the literature to get the answer**
- 5. If you get clear answer, stop searching and formulate other question**
- 6. If you couldn't get answer or you get non-conclusive answer,**
- 7. Formulate a research protocol**
- 8. Data collection**
- 9. Data analysis**
- 10. Manuscript writing (How to write a research paper)**

## **Choose the area of research**

As biomedicine is a broad area, choosing a specific area of interest is crucial. This is the general area within your working field where you intend to conduct your research. For example, if you are an internist, choose the subspecialty which interests you, e.g. neurology, hematology, cardiology...etc.

## **Choose a topic which interests and challenges you**

Choosing your topic is the first and most important step in your research paper project. Focus on a limited aspect and narrow your topic as much as possible. The major topic can be broken down into its components or smaller pieces. For example, if you choose neurology subspecialty, and you choose stroke as a topic, try to narrow your topic as much as possible (e.g., the major topic of stroke may be broken down into risk factors, complications and predictors of mortality).

## **Formulate a research question**

After choosing a topic, formulate a research question, which is a statement that identifies the phenomenon of interest to be studied. For example, if you choose risk factors of stroke as a topic that can be researched; you might ask the following questions:

- What are the main risk factors of stroke in Qatar?
- Is chewing kat a risk factor of stroke in Yemen?
- Is sleep apnea a risk factor of stroke?

Once you complete your list, review your questions in order to choose a usable one which interests and challenges you.

## How to review a literature

Once you select and finalize the research question, you have to do a thorough review of existing literature on the concern topic. This is one of the most important sections of your research. A literature review is an objective, critical summary of published research literature relevant to a topic under consideration for research; it also includes the gaps in the knowledge base. Therefore, it may justify future research into a previously overlooked or understudied area.

### Organize and structure literature review

There are several ways to organize and structure a literature review. Two common ways are chronologically and thematically.

- **Chronological:** In a chronological review, you will group and discuss your sources in order of their appearance (usually publication), highlighting the changes in research in the field and your specific topic over time. This method is useful for papers focusing on research methodology, historiographical papers, and other writing where time becomes an important element.
- **Thematic:** In a thematic review, you will group and discuss your sources in terms of the themes or topics they cover. This method is often a stronger one organizationally, and it can help you resist the urge to summarize your sources. By grouping themes or topics of research together, you will be able to demonstrate the types of topics that are important to your research.

**Ways of finding relevant materials:** Where are you going to find the information to answer your question? The following sources can help you to get the answer:

- **Electronic sources:** By using keywords, search a computer database. It is best to use at least two databases relevant to your discipline. No electronic literature search can be 100% comprehensive, as the match between search terms and the content of articles will never be perfect.
- **Manual searching:** it involves examining reference sources such as catalog lists and indexes, by hand to identify relevant sources for an area of interest.
- **References of references:** Remember that the reference lists of recent articles and reviews can lead to valuable papers.

### Read the selected articles thoroughly and evaluate them

- Has anyone else looked at this question or similar questions?
- What assumptions do most/some researchers seem to be making?
- What methodologies do they use? What testing procedures, subjects, material tested?
- What did they find?
- Record and evaluate the research findings and conclusions drawn

At the end, if you got conclusive answer for your research question, stop searching and choose another question or consider a new topic. If you couldn't get a clear answer or you got non-conclusive answers, provide your hypothesis and move to the next step.

## How to formulate a research protocol

You will need to write a research protocol to accompany your ethics application - whether you submit to local research & ethics committee or through the NHS IRB system. Essentially the protocol serves as an introduction to the project content area and as an explicit guide on all aspects of your proposed methodology. Moreover, it should provide the information needed for reviewers to determine that the regulatory and Human Research Protection Program (HRPP) policy requirements have been met. A good protocol is evidence that you have clarified your research project to the point that when it comes to data collection and analysis, you are confident about the analysis you are going to do and the implications of this analysis on your research questions. A well-written protocol will facilitate the process of obtaining institutional and ethical approval for your research and increase your chances of obtaining funding for your project.

### Structure of research protocol

1. **Project title:** The title should be descriptive and concise. It may need to be revised after completion of the writing of the protocol to reflect more closely the sense of the study.
2. **Project summary/rationale:** This one page summary focuses on the research topic, its new, current and relevant aspects. Strive for clarity; your greatest challenge might be narrowing the topic. In addition, you must answer these two questions: why do you want to conduct this study? What will be its relevance?
3. **Objectives:** Outline concise and precise objectives that should follow on from the hypothesis.
  - **Primary objective:** Include the details of your primary objective (which is your main purpose of performing this study and should be focused on one question). For example: to evaluate the safety and tolerability of single oral doses of compound X in normal volunteers.
  - **Secondary objectives:** Include secondary objectives which can be two or three can be dependent or independent of the primary objective. For example; to assess the pharmacokinetic profile of compound X following single oral doses.
4. **Methodology:** (Design, setting, population, case definitions, sampling and data collection methods)
  - **Study Design** What study design is most appropriate to answer your particular research question?
  - **Setting** Where will the research take place? Your study may take place in a number of different sites.
  - **Subjects/Patients** Detailed information regarding your subjects should be given. For example, describe the study population, including a rationale of why they were chosen. Describe the methods by which subjects will be identified and recruited and what inclusion & exclusion criteria will be used. You will need to justify your sample size and state whether sample size calculations have been

used. It may also be necessary to describe the criteria for participation or completion of the study, participant retention strategies and withdrawal criteria.

- **Inclusion /Exclusion Criteria**
- **Sample:** (Sample size and sampling technique), A sample size or power calculation should be performed. This calculation is used to estimate the number of subjects required to answer your primary study hypothesis with an accepted power. Conversely, it also allows you to estimate what power can be achieved with a limited number of participants. This number is calculated by specifying the magnitude of the effects that are expected (i.e. informed and clinically significant), variability of the measurements and the acceptable degree of type I and II errors. You need to specify the assumptions made for the calculation. It is recommended that you consult with a statistician for this section. Also keep in mind the estimated recruitment rate and whether you need to adjust for anticipated non-responders and losses to follow up. Sampling or sample technique is concerned with the selection of a subset of individuals from within a statistical population to estimate characteristics of the whole population. Two advantages of sampling are that the cost is lower and data collection is faster than measuring the entire population.
- **Outcomes of the Study:** The measurement outcomes used to support or reject the hypotheses can be stated and separated into primary and secondary outcomes. The primary outcome should be the most important and clinically relevant outcome. However, it is also the outcome used to calculate study sample size and power and test the primary research hypothesis. Generally, no more than 1-2 primary outcome measures are pre-specified. Primary outcome measures may be measured in various ways such as: binary (e.g. caesarean/no caesarean, blood loss  $\geq 500\text{mL}$ /blood loss  $< 500\text{mL}$ ); continuous (e.g. weight - kg, blood loss - mL); ordinal (e.g. pain - mild, moderate, severe); time to event (e.g. survival), and counts (e.g. number of infections, number of events occurring). Secondary outcome(s) are measures of additional or less important research interest. They may include additional clinical, psychological, economic, or safety outcomes (e.g. treatment related side effects/adverse events). However, as these endpoints are not used to calculate study power and sample size it is often not possible to draw robust conclusions from the results.
- **Data collection methods:** Describe the instruments used for data collection (Questionnaire, Observation recording form, Survey forms, instruments etc. and studied variables included from these instruments with references should be described. Methods used to test for the validity and reliability of used questionnaire, recording forms and survey forms should also be described) and how the data will be collected.
- **Quality Assurance:** The protocol should describe the quality control and quality assurance system for the conduct of the study, including good clinical practice (GCP), methods used to make sure that data collected is accurate, methods used to ensure reliability and validity, methods used to ensure compliance of research with the research protocol, methods in place for ensuring data safety.

5. **Data management and analysis:** The protocol should provide information on how the data will be managed, including data coding for computer analysis, monitoring and verification. Information should also be provided on the available computer facility. The statistical methods used for the analysis of data should be clearly outlined.
6. **References:** The protocol should end with references relevant to study used in background for review of literature.
7. **Ethical considerations:** The protocol should have a description of ethical considerations relating to the study. This should not be limited to providing information on how or from whom the ethics approval will be taken, but this section should document the issues that are likely to raise ethical concerns. It should also describe how the investigator(s) plan to obtain informed consent from the research participants (the informed consent process). Moreover, how and where the study data will be stored and secured and how will subject's confidentiality be protected, who will have access to confidential research information etc..)
8. **Dissemination of Results and Publication Policy:** The protocol should specify not only dissemination of results in the scientific media, but also to the community and/ or the participants, and consider dissemination to the policy makers where relevant. Publication policy should be clearly discussed- for example who will take the lead in publication and who will be acknowledged in publications, etc.
9. **Timetable:** Develop a time table (if possible in table form), indicating the sequence of research phases and the time that you will probably need for each phase. Take into account that at this stage, it can only be estimated, but make clear that you have an idea about the time span that will be needed for each step.
10. **Budget:** The budget section should contain a detailed item-wise breakdown of the funds requested for, along with a justification for each item.
11. **Other funding agencies:** Is your study funded by another funding agency? (If yes, specify the agency and available funds)
12. **Required reports:** A progress report should be submitted in every 6 months of the project's implementation and a final report at the completion of the project. A list of participants recruited into the clinical trial should be submitted to the MRC at the end of every month where as a progress report should be submitted in every 6 months and final report at the completion of the all types of projects. If the study duration extends beyond a year, an application for extension with progress report must be submitted to the Research Committee to review and renewal of the project. Once research is published, copy of the published article should be submitted to MRC for updating database.



## How to write a research paper

A research paper is an organized essay that presents your research project. An objective of organizing a research paper is to help you to do your job easily and allow people to read your work selectively. The style and format of research papers frequently follow this structure:

- **Title:** The title should be the same as mentioned in the protocol. It may need to be revised after completion of the writing of the research paper to reflect more closely the sense of the study.
- **Abstract:** An abstract is a concise summary (single paragraph or structured) of your work. In a minute or less a reader can pick up the objectives and scope of research, results and principal conclusion gained in your research work.
- **Key words:** These are used for indexing purposes and must be selected from the Index Medicus Medical Subject Headings (MeSH).
- **Introduction:** The purpose of an introduction is to acquaint the reader with the rationale behind the work, with the intention of defending it. It places your work in a theoretical context, and enables the reader to understand and appreciate your objectives.
- **Methodology:** The objective of this section is to provide sufficient detail of theoretical and experimental methods and materials used in your research work, so that another individual may use some or all of the methods in another study or judge the scientific merit of your work. Be precise, complete and concise: include only relevant information. For example, provide a reference for a particular technique instead of describing all the details.
- **Results:** The purpose of a results section is to present and illustrate your findings and is not a place for discussion or interpretation of the data. Combine the use of text, tables, and figures to digest and condense the data, and highlight important trends and extract relationships among different data items.
- **Discussion:** This is your chance to clearly demonstrate the novelty and importance of your research work. By properly structuring this section, you can show how your results can solve the current problems and how they relate to the research objectives that you have described in the Introduction section.
- **Conclusion:** is the last paragraph in your discussion section. It summarizes the important results and impact of the research work. Finish with specific justified suggestions for future research projects if they are beneficial to readers.
- **References:** List all literature cited in your paper; there is a wide variety of styles for citing and listing references. Make sure you follow the instructions for the journal you are submitting your paper to.
- **Tables and figures:** these should generally be included in a separate section after the References section. Tables and figures must be well designed, clear, and easy to read.
- **Tables and figures captions:** Table and figure captions should be succinct yet provide sufficient information to understand them without reference to the text.



## References

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2. Research Methodology in the Medical and Biological Sciences. Peter Laak, Haakon Breien Benestad, Bjorn Reino Olsen. Elsevier/AP. 1st Edition 2007, 483 pages
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