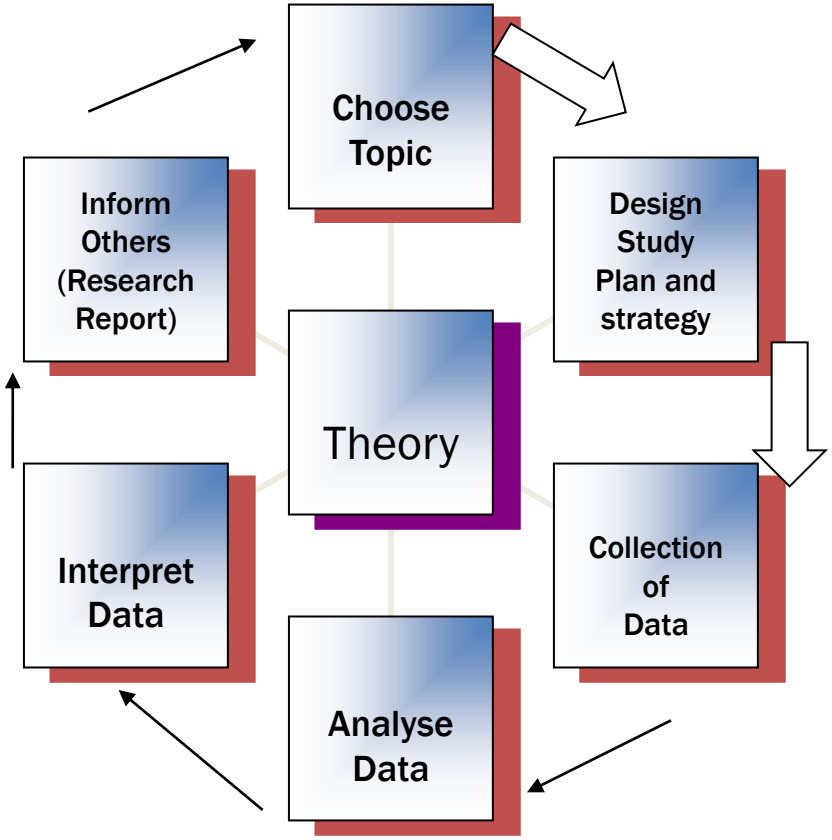
# WRITING RESEARCH PROPOSAL: PLANNING AND PROTOCOL DEVELOPMENT

Dr A.O. Odeyemi

Department of Medicine, Bowen University

# Cycle of Research



# Components of Research proposal

- ***Title page:***
- The title should be explicit
- The title of the research proposal (protocol) should convey the main purpose (research question) of the research
- It should convey maximum information in few words (not more than 12-15 words)
- It should indicate the area of research, introduce the research question and specify the research method to be used.

- ***Abstract:*** Should be concise, outlines content, aim and objective, methodologies, results or main findings and conclusion.

# Introduction

- All protocols start with an introduction section. It is a description of the scientific background to the research question and is logical, based on problem statement and research goal.
- It is a description of the scientific background to the research question and should include the following sections (paragraphs):

# Introduction contd.

1. A statement of the importance of the research area based on, for example,

   the number of people who suffer from the disease being studied or the cost that it presents to the health authorities.

- 2. A brief review of current research

  The introduction should include a brief review of the landmark studies and important recent ones. It is essential to do a literature search (e.g. Medline) to be sure you have covered the literature adequately.

# Introduction contd.

- **3. The need for further (your) research**

  The introduction is not primarily aimed at summarizing present knowledge but must make the case for the need for further (your) research by highlighting the gaps in present knowledge.

- **4. The broad long-term goals (benefits) of the proposed research**

  The introduction often concludes with the broad long-term goals (benefits) of the proposed research.

# Introduction contd.

- ***<u>Problem statement:</u>*** Summarize the problem, It is the demarcation of a problem area within a certain context involving the WHO or WHAT, the WHERE, the WHEN and the WHY of the problem situation and justify why this problem has to be investigated.

# AIM and Objectives

- This section is where you should list the hypotheses that your study will test or the research questions it will address.
- The aim and objectives of your study should be briefly stated. The numbers of objectives should hardly ever be be more than four.
- Do not include objectives for which your study cannot provide results

# Literature review

This is necessary to ensure that the research question is original. What is already known about this subject? What do we need to know? Previous studies can be used to ensure that participant selection, interventions, controls, and outcomes are all appropriate.

# Methods or Methodology?

- Methods are the techniques or procedures used to collect and analyse data
- Methodology refers to discussions of how research is done, or should be done, and the critical analysis of methods of research

# Methodology

- **Study Background**

- **Specify the study design**

  The study design should be given in some detail. Some of the more common designs are: clinical trials, surveys (cross sectional surveys), case-control studies, cohort studies, qualitative studies, economic evaluation.

# Methodology Contd.

**Define the study subjects**

- The study subjects must be described in detail. You should include the following information as well as any other points relevant to your particular study:
- The criteria for including subjects in the investigation (age range, gender, special characteristics related to the condition you are investigating).

# Methodology Contd.

- The criteria for excluding subjects from the investigation (too severely ill, presence of other disease, too old or too young).
- The diagnostic criteria (if relevant).
- The recruitment methods. (from clinic lists, from referral doctors case-notes, from computerized patient lists, electoral role, routinely collected personal records such as birth and death registers etc.).

# Methodology Contd.

**Describe how the data will be collected**

The data to be collected should be specified, indicating how it will be measured. The following are

important aspects of data collection:

- **1. Questionnaires**

  If a postal questionnaire or interview is to be used a list of the items to be covered should be given. It is necessary to have the completed pro forma ready, piloted and clearly designed.

# Methodology Contd.

- **2. Physical measurements**
- If physical measurements are to be made (e.g. peak flow, or blood pressure) the type of equipment which will be used should be described and the manufacturer's name given.

# Methodology Contd.

- **3. Biochemical measures**
- If biochemical measures are to be made (e.g. serum cholesterol, urinary sodium) the analytical techniques which will be used should be described and referenced. If there is no reference, a full description will be required.

# Methodology Contd.

- **Outline the study procedures**

  The logistics of research studies often need careful planning. Reviewers want to know that the following sorts of questions have been addressed and answered:
- How subjects will be identified and contacted?
- What sampling methods will be used?
- Where will subjects be interviewed?
- How will the interviews be organized?

# Methodology Contd.

- Who will carry out the interviews?
- How will the interviewers be trained?
- Some studies involve following patients over time and these need to describe how follow-up contacts will be organized.
- For randomized controlled trials, the method of randomization must be described.

# Methodology Contd.

- **Describe sample size calculation**

  Formal sample size calculations are required for all research studies. These indicate how many study subjects are needed so that, if the research ideas are correct, it is very likely that a statistically significant result will be obtained. If the study is too small a real effect may be overlooked. If it is too large, resources will be wasted.

- A reference should be made to the method used for the calculation.

# Methodology Contd.

- **Describe briefly the statistical analysis**
- A limited description is needed of the statistical techniques, which will be used. It is usually sufficient to mention a few techniques, such as chi-squared tests, analysis of variance, multiple regression, logistic regression.
- If the statistical analysis is likely to be extensive it might be best to have a statistician as a supervisor or co-supervisor.

# ETHICS

- Any study that involves altering normal patient management or asking patient to do anything beyond routine care (even completing a questionnaire) will need ethics committee approval. Information and consent procedures should be described
- The main ethical concerns are;
  - whether the research will place the patients under undue risk, and;
  - Whether the subjects are fully informed about the nature of the study.

# Consent Form

- Lay language
- Reason for the study
- What specifically is being tested
- Why was the subject selected
- What exactly is required of participants
- Potential risks / potential benefits
- Anonymity
- Right to decline or withdraw
- Who to contact if concerns
- Copy for patient

# Summary of Writing Research Proposal

- Title
- Introduction (inc. statement of research problem/ question/ aims objectives)
- Literature Review
- Research Design

- Method of data selection
- Instruments/ techniques to be used
- Data analysis strategy
- Ethical issues
- Timeline
- Resources required
- Expected outcomes of research

# REFERENCES

- The Vancouver style for references is recommended as it is used by almost all medical journals. It uses numbers in the text and lists the references in numerical order.
- References are numbered in the order in which they appear in the protocol.
- In the list of references you should give the names and initials of all authors.

# REFERENCES (contd.)

- The authors' names are followed by the title of the article and the title of the journal abbreviated according to the style of Index Medicus; then the year of publication; the volume number: and the first and last page numbers.
- References to books should give the names of any editors, place of publication, edition, and year.
- Information from manuscripts not yet in press, papers reported at meetings, or personal communications should be cited only in the text, and not as a formal reference.

***Thank you***