

## Objectives:

1. Understand the different steps of a research protocol and its importance.
2. Develop a research protocol of their topic of interest.

# Introduction to research And How to develop a research protocol

Editing file



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**Editing file**

Black: in male AND female slides

Red : important

Gray: extra information



# Research

Research is the **systematic collection, analysis** and **interpretation** of data to answer a certain question or solve a problem

## RESEARCH PROTOCOL

### Definition

it's basically a document that contains a description of everything in the research, Background, rationale, objectives, design, methodology and the organization\*

Reasons to have a protocol:

- The reason for having a study plan or protocol is *efficiency* in carrying out the study.
- Able to do the intended study quickly, cheaply, easily and ethically.

### Example of protocol outlines

Element	Purpose
<b>1- Research questions</b>	What questions will the study address?
<b>2- Significance (background)</b>	Why are these questions important?
<b>3- Design Time frame Epidemiologic approach</b>	How is the study structured?
<b>4- Subjects Selection criteria Sampling design</b>	Who are the subjects and how will they be selected?
<b>5- Variables Predictor variables Confounding variables Outcome variables</b>	What measurements will be made?
<b>6- Statistical issues Hypotheses Sampling size Analytic approach</b>	How large is the study and how will it be analyzed?

## Components of research protocols

Anatomy of research (what it's made of)	Physiology of research (how it works)
<ol style="list-style-type: none"><li>1) Research question</li><li>2) Significance</li><li>3) Design</li><li>4) Subjects</li><li>5) Population</li><li>6) Sample size</li><li>7) Variables</li><li>8) Predictor</li><li>9) Outcome</li></ol>	Using measurements in a sample to draw inferences about phenomena in a population

### Why we need a Protocol?

- To clarify the research question.
- To compile existing knowledge.
- To formulate a hypothesis and objectives.
- To decide about a study design.
- To clarify ethical considerations.
- To apply for funding.
- To have a guideline and tool for the research team.

### How to judge a good protocol?

- Is it adequate to answer the research question, and achieve the study objective?
- Is it feasible in the particular set-up for the study?
- Does it provide enough detail (methodology) that can allow another investigator to do the study and arrive at comparable conclusions?

## Title of a research project

- Accurate, short, concise.
- Descriptive: should make the main objective clear, should mention the target population.
- Key words: should contain key words for referencing.
  - i.e. TB in HIV – infected children
  - Better: Incidence of TB in HIV- infected children in South Africa during 2017-2018“

## Project summary

- Concise to one page ( $\approx$ 300 words).
- Stands on its own – no reference to protocol content.
- Summarizes central elements
  - i.e. Rationale, methodology, populations, timeframe, and expected outcomes.

## Protocol Problem

Statement of the problem :-

It is defined as : An inquiry starting from given conditions to investigate or demonstrate a fact or result.\*

Answers why your research is needed, and what the relevance of your results is.

Also called your 'Rationale' or 'Justification'\*

1. Magnitude, frequency, and distribution: Who is affected (Age-group, ethnic, gender considerations), and Where (geographical considerations)?
2. Probable causes: What is the current knowledge of the problem and its causes?
3. Is there consensus? Is there controversy? Is there conclusive evidence?
4. Possible solutions: In what ways have solutions to the problem been attempted?
5. What has been proposed? What are the results?
6. Unanswered questions: What remains to be answered? What areas have not been possible to understand, determine, verify, or test?
7. Based on the points you will mention above, you develop your objectives.

# Literature review

**Definition :** A summary of previous research done on a topic.\*

it Aims to :

- Prevents duplication of work, which has been done
- Clarifies, what others have found addressing the problem
- Familiarizes with potential methodologies and methodological errors
- Should convince, that the research is needed!

## Justification of research

Should be a convincing statement for the need to do this research

- How does the research relate to the priorities of the region and the country?
- What knowledge and information will be obtained?
- What is the ultimate purpose that the knowledge obtained from the study will serve?
- How will the results be used, and who will be the beneficiaries?

## Research objectives

**Definition :** Description of what you expect to achieve by a research\*

Define a GENERAL OBJECTIVE (Primary) and derive SPECIFIC OBJECTIVES from it.

The formulation of objectives will help to:

- Focus the study (narrowing it down to essentials).
- Avoid the collection of data which are not strictly necessary for understanding and solving the problem you have identified.
- Organize the study in clearly defined parts or phases.

Objectives should be:

- Logical and coherent
- Feasible
- Realistic, considering local conditions
- Defined in operational terms that can be measured
- Phrased to clearly meet the purpose of the study (relevant)

Objectives should be stated in action verbs that illustrate their purpose:

i.e. "To determine..., To compare..., To verify..., To calculate...,To reduce..., To describe..., etc.

## Research hypothesis

- Describes the relationship between INDEPENDENT variables (risk factors, predisposing factors) and DEPENDENT variables (outcome).
- Determines the type of data to be collected and the type of analysis to be conducted.



## Epidemiology :

Important aspect of the protocol (Why?)

- Assures, that the hypothesis will be proved or disproved, using the **right tools**.
- Presents a **detailed strategy**, how the objectives are achieved.

Consider:

- operational definitions
- study design
- definition of variables
- sample size
- ethical aspects

## Study Design

### Interventional study

- ✓ Clinical trial

### Observational study

- ✓ Cohort study
- ✓ Cross-sectional study
- ✓ Case – control study
- ✓ Ecological study

# Study Design

Conceptual definition of variable	Operational definition (Indicator)	Scale of measurements
<b>Age</b>	Age at last birthday	Continuous: in months
<b>Family Size</b>	Number of family members	Discrete
<b>Use of clinic</b>	Number of visits to clinic	Discrete
<b>Haemoglobin</b>	Haemoglobin Concentration in capillary blood, measured by Haemoglobinometer	Continuous: e.g, grams per 100ml, rounded off to nearest gram
<b>Nutritional Status</b>	Weight in relation to age compared to standard growth curve	Ordinal: e.g., <ol style="list-style-type: none"> <li>1. Well nourished=&gt;80% of standard</li> <li>2. Moderately malnourished = 60% to 80% of standard.</li> <li>3. Severely malnourished = &lt;60% of standard</li> </ol>
<b>Patient's satisfaction</b>	Response to a specific question about his/her satisfaction with services obtained, put to patients on discharge.	Ordinal: e.g., <ol style="list-style-type: none"> <li>1. Very satisfied</li> <li>2. Somewhat satisfied</li> <li>3. Somewhat dissatisfied</li> <li>4. Very dissatisfied</li> </ol>
<b>Immunisation Coverage</b>	Percentage of children immunised in particular age group	Continuous: e.g., Percentages or ordinal <ul style="list-style-type: none"> <li>○ High &gt;80%</li> <li>○ Medium 60% - 80%</li> <li>○ Low &lt;60%</li> </ul>
<b>Religion</b>	As reported by informants	Nominal; Christian, muslim, hindu
<b>Main source of Carbohydrate in the Diet</b>	Main type of staple food eaten	Nominal: Maize, rice, Millet, Cassava...

# Measurement of observations

- Describe **how**, **when** and **where** the observations are made? Describe instruments used!
  - Questionnaire (attach to the protocol)
  - Type of interview (describe structure of the interview)
  - Laboratory test (refer to literature or personal knowledge if established test, or describe in detail, if not established)
  - Clinical examinations (describe gadget/procedure), Describe all instruments or refer to literature if tools are established.

**(for intervention studies or drug trials refer to specific literature/regulations)**

## Subjects/ participants

Depending on the **type of study**, answer the following questions:

- What are the **criteria for inclusion** or selection?
- What are the **criteria for exclusion**?
- In intervention studies, how will subjects be allocated to index and comparison groups (Randomization procedure)?
- What are the **criteria for discontinuation**?

## Sample size

- Sample size calculation is recommended for **economical** and **ethical** reasons.
- Simple statistical packages in the internet.
- Level of error, power and expected impact of exposure on outcome have to be set.

## Work plan

ACTIVITY	WHO	JAN	FEB	MARCH	APRIL	MAY
Meeting with clinic staff	All Project Staff					
Meeting with District Management	All Project Staff					
Design Questionnaire	Researcher					
Train Field Workers & Pilot Questionnaire	Researcher and Field Workers					
Data Collection	Researcher and Field Workers					
Analysis	Researcher					
Meeting with Clinic Staff and District Management	All Project Staff					
Write up Full Report	Researcher					
Write article for Update and Policy Brief	Researcher					
Meeting with Clinic Staff and District Management	All Project Staff					

Who?

When?

Where?



# Ethical considerations

## Informed consent:

- Outline **how, when and where** the patient will be consented!
- Information form should contain:
  - Justification for research
  - Responsibilities (Who)
  - Outline of study
  - Confidentiality (legal framework)
  - A separate consent form is required!

## Ethics checklist:

- Should answer potential questions regarding the ethics
- Should discuss pros and cons of research design, selection of subject, measurement and outcome assessment.
- Should discuss the advantages and disadvantages of the subject or communities involved
- Should discuss physical, social and psychological implications of the research
- Should discuss confidentiality

# Data management and analysis

## Based on **objectives** consider:

- Coding for variables/ type of variables
- Analysis plan depending on type of variables
- Appropriate Statistical tests
- Style of presentation (tables, graphs)

# References/Bibliography

## Use of **standard referencing system**:

- **Vancouver style** everyone should do this style, most journal accept it.
  - Numbered references
  - Continuous referencing in text
- *Harvard style*
  - Name and publication year in text
  - Alphabetical bibliography

## Make use of **software**

- Reference Manager
- Endnote software

# Budget

The budget should be broken down by:

## Items

- Personnel
- Consumables, equipment, supplies, communication, funds for patients, data processing.

## Budget justification

- Justify the use of each item, considering the work plan of the study.

## Annexes

an addition to a document.

## Common mistakes

- Case Record Forms (CRFs)
- Questionnaires
- Consent form (in required languages)
- Including too little detail about proposed studies and insufficient justification for the significance of the problem.
- Proposing far more work than can be reasonably done during the grant period.

# Lecture Summary

## Elements of Research Protocol

- |                     |                      |
|---------------------|----------------------|
| 1-Research question | 2-Significance       |
| 3-Design            | 4-subjects           |
| 5-Variables         | 6-Statistical issues |

## Why we need a Protocol?

- |                                      |                                |
|--------------------------------------|--------------------------------|
| -Clarify the question                | -Apply for funding             |
| -Compile existing knowledge          | -Clarify ethical consideration |
| -Formulate Hypothesis and objectives | -Decide the study design       |

## How to judge a good protocol?

- Is it adequate to answer the research question
- Is it feasible in the particular set-up for the study?
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## Why we need Objectives?

- Focus the study (narrowing it down to essentials).
- Avoid the collection of data which are not strictly necessary for understanding and solving the problem you have identified.
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## Why we need Literature review?

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# Questions

**(1) the significance of research is:**

- A) why the question is important?
- B) How it would affect the researcher
- C) How the research would be conducted
- D) How it would affect the Subjects

**(2) which one of these is an Interventional study?**

- A) Cohort
- B) Cross-sectional
- C) Case report
- D) Clinical trials

**(3) Why we need Objectives?**

- A) Focus the study
- B) Organize the study
- C) prevents the collection of unnecessary data
- D) All of the above

**(4) one of the benefits of Literature review:**

- A) Prevents duplication of work
- B) Increases the chance of duplication
- C) Leads to plagiarism
- D) loss of interest

**(5) which one of these is an element of Protocol?**

- A) Research question
- B) Subjects
- C) Significance
- D) All the above

**(6) the analysis plan depends on**

- A) Subjects alone
- B) The equipments
- C) Ethics checklist
- D) type of variable

Answers:

1: A, 2: D, 3:D, 4:A, 5:D, 6:D

# Lecture notes 439 ...

**R.P :**

**What is the research**

**- key points of your proposal:**

**Think by why , where , when , who's , what.**

**Protocol: is the reason for having a plan like marriage: you plan first —> look for work , money...etc you must have plan .**

**Protocol outlines.ex : what's the time you go bed -**

**Elements of protocol outlines :**

**- Research question: how to help by study**

**- Significance : what is the important, gab , how to fill it ?**

**- Design: what is your type of design is it cross-section ? Or case report.**

**- Subjects : how are you going to take your sample**

**- Variables: what , how you measure , what are you going to use , what the sample size...etc**

**Physiology of research: not all suffering are you gonna take random sample? Ex : what is your study HTN? You need to know your sample**

**- 3 criteria to judge if the written is good or no :**

**- adequate to achieve the objectives? To answer the research question?**

**- Is it feasible**

**- Provide enough details?**

**Statement of problem :**

**Unanswered Questions: if you're reading an article looks for the gabs**

**Methodology:**

**What are you going to**

**1- Study design**

**Interventional : clinical trial (ex:vaccines)**

**Observational: cross section mostly used**

**2-measurement: what is your variables? How to measure them?**

**Data management: after finishing data collection now how you will analyze them ? What is your next ? What is your plan for analysis?**

**Reference/bibliography :**

**Standard referencing system:**

**- Harvard ( few journals ask for it)**

**- Vancouver ( most of journals ask for it )**

## Leaders



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