



# How to develop a research protocol

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# Objectives of this session

Able to:

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



# ***What is research?***

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

# Protocol

- The reason for having a study plan or protocol is efficiency in carrying out the study.
- You want to be able to do the intended study quickly, easily and ethically.
- Here is a example of protocol outlines

# Study protocol outline

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

## the process of research in familiar terms:

### ■ **Anatomy of research** (what it's made of)

- • **Research question**
- • **Significance**
- • **Design**
- • **Subjects**
- – **Population**
- – **Sample size**
- • **Variables**
- – **Predictor (Independent)**
- – **Outcome (Dependent)**

### ■ **Physiology of research** (how it works)

- **Using measurements in a sample to draw inferences about phenomena in a population**

# ***Why 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(s), 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, one page (about 300 words)
- Stands on its own – no reference to protocol content
- Summarizes central elements (rationale, methodology, populations, time frame, expected outcomes)

# ***Statement of the problem***

- Why ...is the research needed?
- What ...is the relevance of the results?

*Logical flow of statements:*

**Magnitude, frequency, and distribution:** Affected geographical areas and population groups. Ethnic and gender considerations.

**Probable causes of the problem:** What is the current knowledge of the problem and its causes? Is there consensus? Is there controversy? Is there conclusive evidence?

**Possible solutions:** In what ways have solutions to the problem been attempted? What has been proposed? What are the results?

**Unanswered questions:** What remains to be answered? What areas have not been possible to understand, determine, verify, or test?



# Literature review

- 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*

Define a **GENERAL OBJECTIVE** and derive **SPECIFIC OBJECTIVES**

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



# *Research objectives*

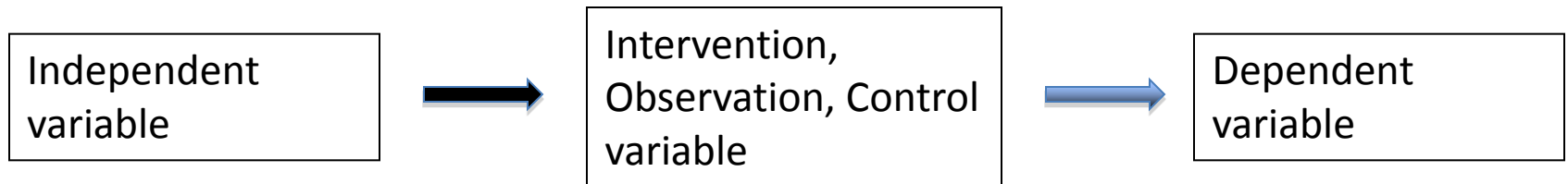
Objectives should be:

- 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





# ***Methodology***

Important aspect of the protocol

- 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



# ***Methodology***

## **Study design**

### **Interventional study**

Clinical trial

### **Observational study**

Cohort study

Cross-sectional study

Case – control study

Ecological study

# Methodology

## Definition of variables

Conceptual definition of variable	Operational definition i.e., indicator	Scale of measurement
Age	Age at last birthday	Continuous: in months
Family size	Number of family members	Discrete
Use of clinic	Number of visits to clinic	Discrete
Haemoglobin	Haemoglobin concentration in capillary blood, measured by haemoglobinometer	Continuous: e.g., grams per 100 ml., rounded off to nearest gram
Nutritional status	Weight in relation to age compared to a standard growth curve	Ordinal: e.g., 1. well nourished = >80% of standard 2. moderately malnourished = 60% to 80% of standard 3. severely malnourished = <60% of standard
Patient's satisfaction	Response to a specific question about his/her satisfaction with services obtained, put to patients on discharge	Ordinal: e.g., 1. very satisfied 2. somewhat satisfied 3. somewhat dissatisfied 4. very dissatisfied
Immunisation coverage	Percentage of children immunised in a particular age group	Continuous: e.g., percentages; or ordinal, e.g., • high > 80% • medium 60% - 80% • low < 60%
Religion	As reported by informants	Nominal: Christian, Moslem, Hindu, Buddhist, etc.
Main source of carbohydrate in the diet	Main type of staple food eaten	Nominal: e.g., maize, millet, rice, cassava, etc.

# *Methodology*

## **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)



# ***Methodology***

## **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?



# ***Methodology***

## **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



# ***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!



# ***Ethical considerations***

## **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 i.e. tables, graphs)



# ***References/Bibliography***

- Use of standard referencing system:
  - *Harvard style*
    - Name and publication year in text
    - Alphabetical bibliography
  - *Vancouver style*
    - Numbered references
    - Continuous referencing in text
- Make use of software
  - Reference Manager
  - Endnote software

# Work plan

Tasks

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?



# ***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 workplan of the study



# ***Annexes***

- Case Record Forms (CRFs)
- Questionnaires
- Consent form (in required languages)



# Common mistakes

- 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



***Thank you !***