How to write Materials & Methods Section of a Research Protocol

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#### منهجية البحث

#### Research Methodology

Study Design: (تصميم الدراسة)

(مدة الدراسة) Study Duration

Study Setting: (إعداد الدراسة)

Target Population/Sample Size: (السكان المستهدفين / حجم العينة)

Inclusion Criteria: (معايير الاشتمال)

Exclusion Criteria: (معايير الاستبعاد)

Study Variables: (متغيرات الدراسة)

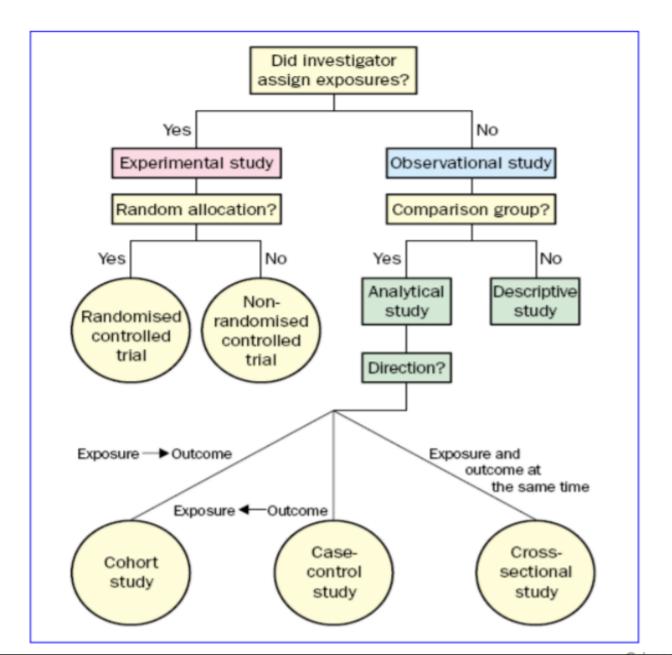
Ethical Considerations: (الاعتبارات الاخلاقية)

Data Collection/Data Source: (جمع البيانات / البيانات المصدر)

Questionnaires/data Sheets from other authors (Copyrights or permission to use, or open access for academic and research purpose)

Statistical Analysis: (تحليل احصائي)

# **Epidemiologic Study Designs**



# Research Designs

Purpose	Study Design
To determine frequency & burden of a disease	* Cross sectional survey (Prevalence)
	* Cohort study (Incidence)
To identify the risk factors	* Cohort study
	* Case-Control study
To determine prognosis of a disease	* Cohort study
To determine efficacy/ effectiveness of new treatment	•* Clinical trials
	•*Community intervention
To evaluate community programs	* Evaluation

# **Study Duration**

- √ Weeks
- ✓ Months
- √Years

# **Study Setting**

■ Where are you going to do the research?

## Target Population/Sample Size

- Who is selected to participate in the study?
- Proper definition of eligibility, inclusion, exclusion and discontinuation criteria of the study subjects should be stated
- The inclusion and exclusion criteria should be clearly defined
- Sample size calculation is recommended for economical and ethical reasons

## Target Population/Sample Size

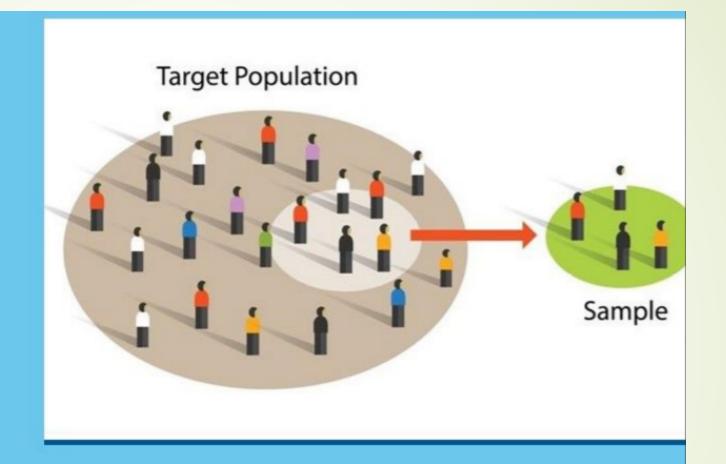
- The calculation of the sample size must be explained including the power of the sample
- The sampling technique should be mentioned, e.g., randomization that will be used in order to obtain a representative sample for your target population
- Each step involved in the recruitment of the study subjects should be described according to the selection criteria (inclusion and exclusion criteria)

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**Project Sample Size for Thesis Research Paper Proposal** 

## **Study Variables**

### Variable

 characteristic which is subject to change and can have more than one value such as age, intelligence, motivation, gender, etc

## Study Variables

- Dependent and Independent Variables
  - Independent variables
    - are variables which are manipulated or controlled or changed
    - It is what the researcher studies to see its relationship or effects
    - Presumed or possible cause
  - Dependent variables
    - are the outcome variables and are the variables for which we calculate statistics
    - The variable which changes on account of independent variable is known as dependent variable

## **Study Variables**

- Example
- Higher education typically leads to higher income
  - ► Higher education---(..... variable)
  - Higher income----( ..... variable)

#### **Ethical Considerations**

- The study will be conducted after Institutional Review Board (IRB) approval
- Informed consent will be given to the subjects before taking the decision to participate; the privacy and confidentiality of subjects' information will be guaranteed and protected by researchers
- The collected data is going to be used only for research. The information will be kept anonymous, and the participation is voluntary

## Data Collection/Data Source

- Qualitative Deals with descriptions
  - Data can be observed Data can not measured e.g. -Colour

- Quantitative Deals with numbers
  - Data which can be measured. e.g. -height, weight, length

## Data Collection/Data Source

- Sources of Data
  - External sources
  - Internal sources
  - Primary data
  - Secondary data

## Data tool

- Retrospective data (medical records)
- Questionnaires
- Interviews (Structured, Semi-Structured)
- Laboratory
- Clinical examinations
- Description of instruments, tools used for data collection, as well as the methods used to test the validity and reliability of the instrument should be provided

## Data Management and Analysis

- This section should be written following statistical advice from a statistician
- The analysis plan and which statistical tests will be used to check the significance to the research question/hypothesis with appropriate references should be described
- Names of variables that will be used in the analyses and the name of statistical analysis that will be performed to assess the outcome should be listed
- If computer programs are to be applied, it is important to mention the software used and its version

## Strengths and Limitations

- It is important to mention the strengths or limitations of the study,
  - what study can achieve or cannot achieve is important,
  - so as to prevent wasteful allocation of resources.

# Thank You and Questions



