HOW TO WRITE A STUDY PROTOCOL

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What ?

Every Step of a Study

- A document that explicitly states
  - Reasoning behind
  - Structure of a research project.

Why?

- To state your research question
- To plan & see whole study in detail, before you start. Check if:
  - Objectives can be achieved
  - Study Feasibility
  - Prevent failure to collect crucial information.
- Acts as a guide & reminder to you & your supervisor (or co-workers) of initial structure & aims of study.
- To monitor progress of study.
- It is necessary to:
  - Obtain approval of ethical committee(s)
  - Application for funds

How to Start ?

- To create a Research Problem:
  - Ideas from colleagues
  - Ideas from similar published studies
  - Good examples
- Use a checklist of items to include
- Get the requested format (grant application)

Protocol Outline

1. Presentation
2. Background & justifications
3. Objectives
4. Material & Methods
5. Ethical considerations
6. Project management
7. Timetable
8. Resources
9. References
10. Appendices

1. Presentation

- **Covering Page Should include:**
  - **Title**
  - **Researcher name, position, purpose, field**
  - **Supervisors: by seniority**
    - **Name**
    - **Position**
    - **Main centres (Department, University)**
  - **University & Year**

This Page is Translated to Make a Covering Page in ARABIC

Title

- Title is one of most important features because it is the 1st to attract attention of reader.
- It must be CATS
  - Concise
  - Accurate
  - To the point
  - Short

Example

- See This Title:

  “An investigation to evaluate the effect of the Herbst and Twin Block functional appliances on skeletal growth during the treatment of Class II skeletal growth anomalies. A randomized controlled trial."

  - It is overlong
  - States the obvious in a rather ‘wordy’ way.
- A preferable approach may be:

  “A randomized trial of Herbst and Twin Block appliances on skeletal growth.”
- This title
  - Comes straight to the point without stating the obvious.
  - It not only attracts the attention of a reader, but it immediately tunes them into the subject matter.

Example

- “Medical cost estimation study regarding management of the most common malignancies among Egyptian females (aged 18 years or above) attending the National Cancer Institute, Cairo University.”

Better title:

- “Cost estimation of most common women cancers at National Cancer Institute.”

2. Background & Justification

- Statement of problem, study justification
  - Importance of subject area
    - Magnitude, Frequency, Impact
  - Highlight Good points & Gaps in quoted studies
  - Principal questions to be addressed
  - Contribution of results to existing knowledge
- Review relevant literature

Other Section Names
Introduction
Rationale
Literature Review

Background

- A brief & to the point.
- No longer than two pages of A4 paper.
- Keep in mind:
  - There are Arab & Egyptian studies !!
  - Previous results may not be accurate or true
  - Don’t be too critical of previous investigators; research technology and data analysis are fast-moving fields
  - Literature must not be old (within last 10 years)

Writing Style

- **Make your writing flow.**
- **It is not A list of papers:**

  ‘X1 has shown that ……., X2 used …… and showed …….. This is in agreement X3 who stated …….. However, X4 have suggested that ……..’.

Writing Style

It is better to take the following approach:

- **There have been many investigators have concluded that ……. *(X1, 2003; X2, 2004; X3, 2006).* However, X4 *(2004)* has suggested……**

- The literature review should logically lead to the statement of the aims of the proposed study.

3. Objectives (Aim of The Work)

- Should answer the study question
- S.M.A.R.T.
  - **S**pecific
  - **M**easurable
  - **A**ttainable
  - **R**eliable
  - **T**ime limited
- Goal: General, can not be measured, broad
- Principal objective
  - Must be achieved
  - Dictates design and methods
- Secondary objectives
  - Of interest, but not essential

Example

- Principal objective

  To determine if sharing a haemodialysis machine with a HCV infected patient is a risk factor for HCV infection.

- Secondary objective:

  To identify failures in procedures designed to prevent cross-infection via haemodialysis machines

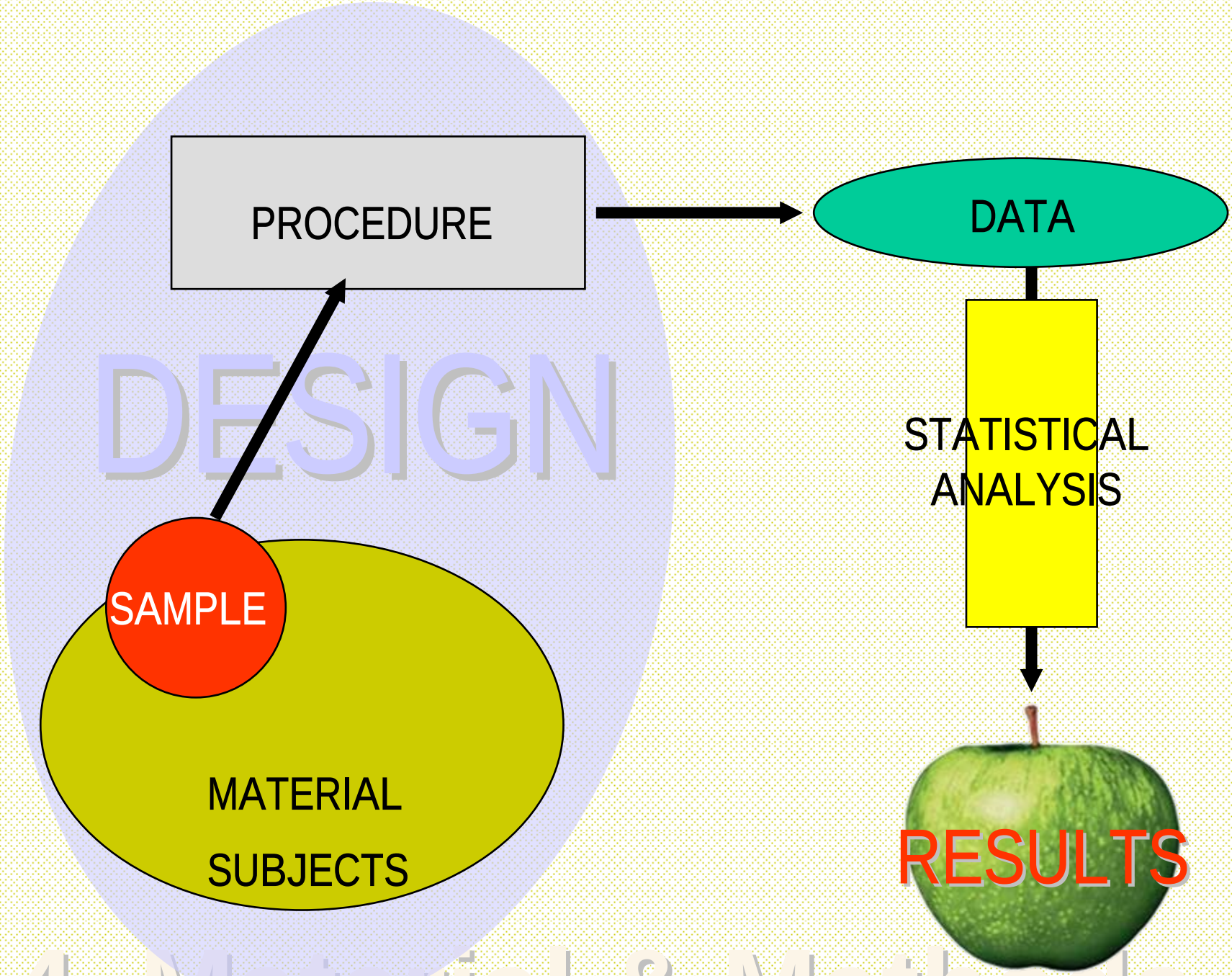
4. Material & Methods

What will be done ? How? Where? When?

- Description of tactics of research
- Probably the easiest part of a research protocol to prepare.
- Use active voice, in the future tense.
- For example:
  - ‘The subjects are randomly allocated to treatment & placebo groups, stratified by age and sex’.

  It will be easier to read:

  - ‘We will randomly allocate the subjects to treatment and placebo groups, stratifying on age and sex'.



4. Material & Methods

1. Design
2. Subjects
3. Procedure
4. Statistical methods

Study Design

- Types of studies:
  - Observational
    - Case-Control
    - Cross-sectional
    - Cohort
  - Experimental (Interventional)
    - In Human Beings, called Clinical trials

1. Design
2. Subjects
3. Procedure
4. Statistical methods

Subjects (Material)

- Not all the study population are patients, some are healthy controls, So better say SUBJECTS
- You should report the following
  - **Definitions (Who?)**
  - **Selection (Where?, How?, When?)**

Definitions

- Population: the subjects will be drawn from
  - Case
  - Control (other disease, normal subjects)
- Exposures
- Risk factors
- Outcomes (CR, PR, DP)
- e.g.: smoking ? lung cancer
  - smoking: definition, quantification, categories
  - lung cancer cases definition
  - control group definition

Who?

Selection

- **Sampling design**
  - Frame: district, household, persons,… **(Where?)**
  - Inclusion and Exclusion Criteria
  - Method: simple random, cluster, stratified,… **(How?)**
  - Randomisation procedures
  - Replacement procedures (in case of refusal)
  - Duration: Time period, Accrual time, follow up **(When?)**
- **Sample size:**
  - Total number & number in subgroups (study, control)
  - Calculations based on principal objective
  - Feasibility
  - May not be specified (all patients coming to outpatient clinic during period from 1st June till end of September 2001)

- If the sample size is too small, the study may not be powerful to detect a difference between the groups, if a true difference exists, so

(I can not infer or generalize my results).

- Therefore, the study would be
  - Worthless
  - Great effort will be wasted.

1. Design
2. Subjects
3. Procedure
4. Statistical methods

Procedure (Methods)

- This will describe exactly what you are going to do with the subjects.
- This includes details of
  - Materials (e.g. Kits)
  - Measurements (items and units)
  - Apparatus used
  - Treatments
  - Method of data collection.

What?

Data collection

- How
  - interview, observation, record review
- By whom
  - interviewers: selection, training
  - level of supervision
- Tools
  - Questionnaires (self or interviewer administered, face to face or telephone interview)
  - Recording materials
- Anonymous data collection

Data Handling

- Coding
  - During data collection, afterwards?
  - By whom?
- Processing
  - Software, hardware
  - Entry
    - During the study, afterwards?
- Validation and data cleaning

Data Analysis Plan

- Structured in terms of
  - Objectives
  - Hypotheses
  - Dummy tables
- Statistical methods

	Cases		Controls		OR
	Exposed	% exp	Exposed	% exp	
Age group					
< 15					
15 – 25					
26 - 60					
> 60					
Sex					
M					
F					
Occupation					
Residence					
Smoking					

1. Design
2. Subjects
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Statistical Methods

- Outlined in detail (not names of the tests)
- Why these tests ? justify
- State:
  - Descriptive method.
  - Dependent variable; e.g. outcome, i.e. alive or dead
  - Independent variables; study group, sex, age, compliance, stage, grade
  - Before analysis, check for fulfillment of assumptions for statistical methods
  - Level of significance
  - Software to use

Pilot studies

- Pre-test your study:
  - Feasibility of sampling
  - Data collection, measurement methods
  - Questionnaire
- Describe how to test
- Correct according to the results of this pilot study

5. Ethical Considerations

- Informed consent
- Confidentiality
- Data storage and protection
- Ethical committee

6. Project Management

- Participating institutes and persons
- Responsibilities and tasks of each partner
- Data ownership

7. Timetable

- Planning/organisation
- Questionnaire, design
- Permission
- Funding
- Pilot study
- Final study
- Data collection
- Analysis
- Presentation of results and write up

8. Resources

- Extent of this section depends on target audience
- Specify
  - available sources
  - requested sources
- Keep budget
  - reasonable
  - detailed
  - well justified

9. References

- Limit number of references to key articles
- Should not be very old except in facts
- Follow recommended style, e.g.
  - English way:

  Rick, F.M.; Rocha, G.C.; Dittmar, K.; Coimbra, C.E. Jr.; Reinhard, K.; Bouchet, F.; Ferreira, L.F. and Araujo, A. (2002): Crab louse infestation in pre-Columbian America. J Parasitol.;88(6):1266-7.

  - American way

  Markl ID, Jones PA. Presence and location of TP53 mutation determines pattern of CDKN2A/ARF pathway inactivation in bladder cancer. Cancer Res 1998;58:5348-53.
- Arrangement

10. Appendices

- Methodological appendices
- List of definitions
- Questionnaires
- Forms for informed consent

Common Problems

- Too ambitious: too many questions
- Poorly formulated objectives
- Insufficient attention to literature
- Poor justification
  - why is it important to answer this question?
  - what impact does it have on public health?
- Potential sources of biases (selection & information bias)
- Inappropriate analysis methodology
- Absence of pilot