How to develop a research protocol

Objectives:

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

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Resources:

• 436 Lecture Slides + Notes

Important – Notes

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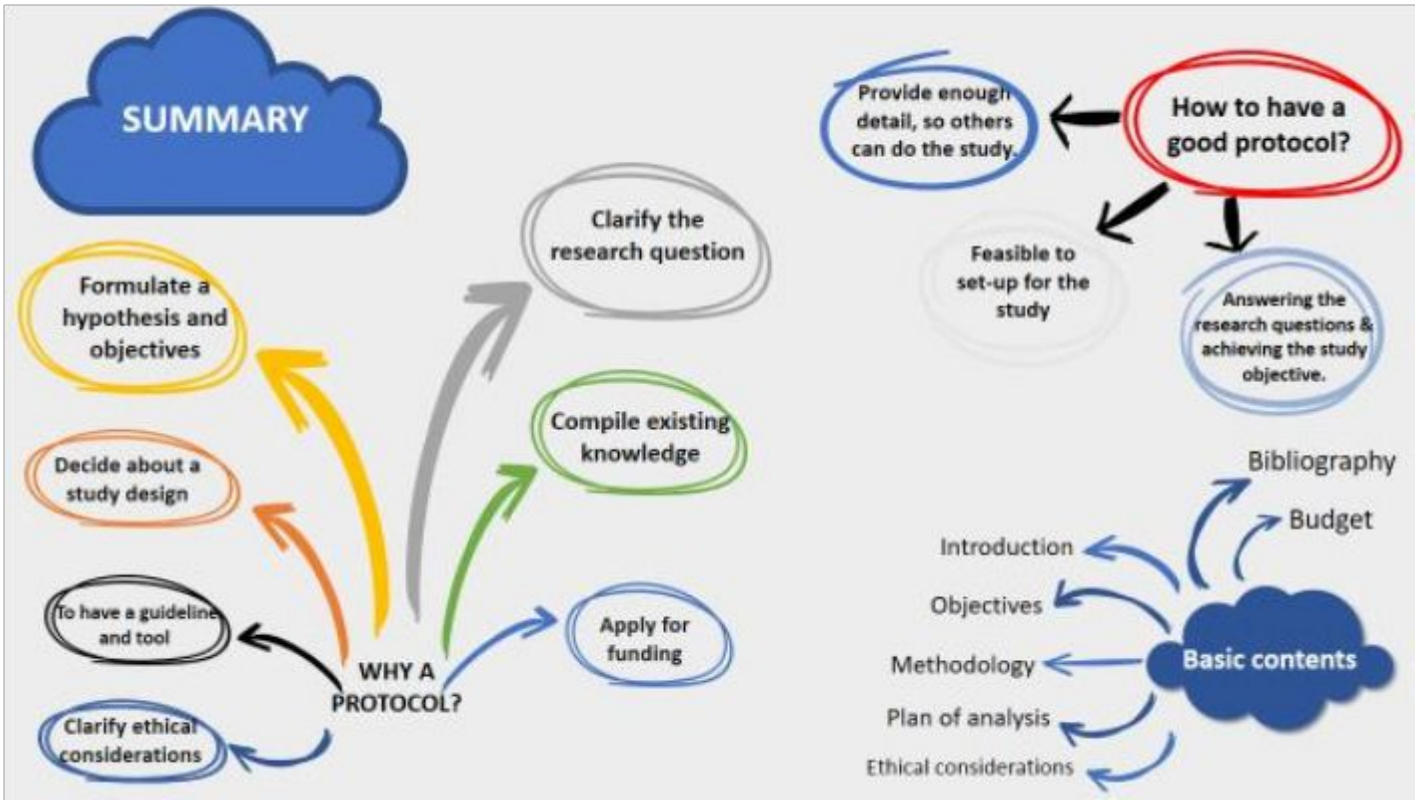
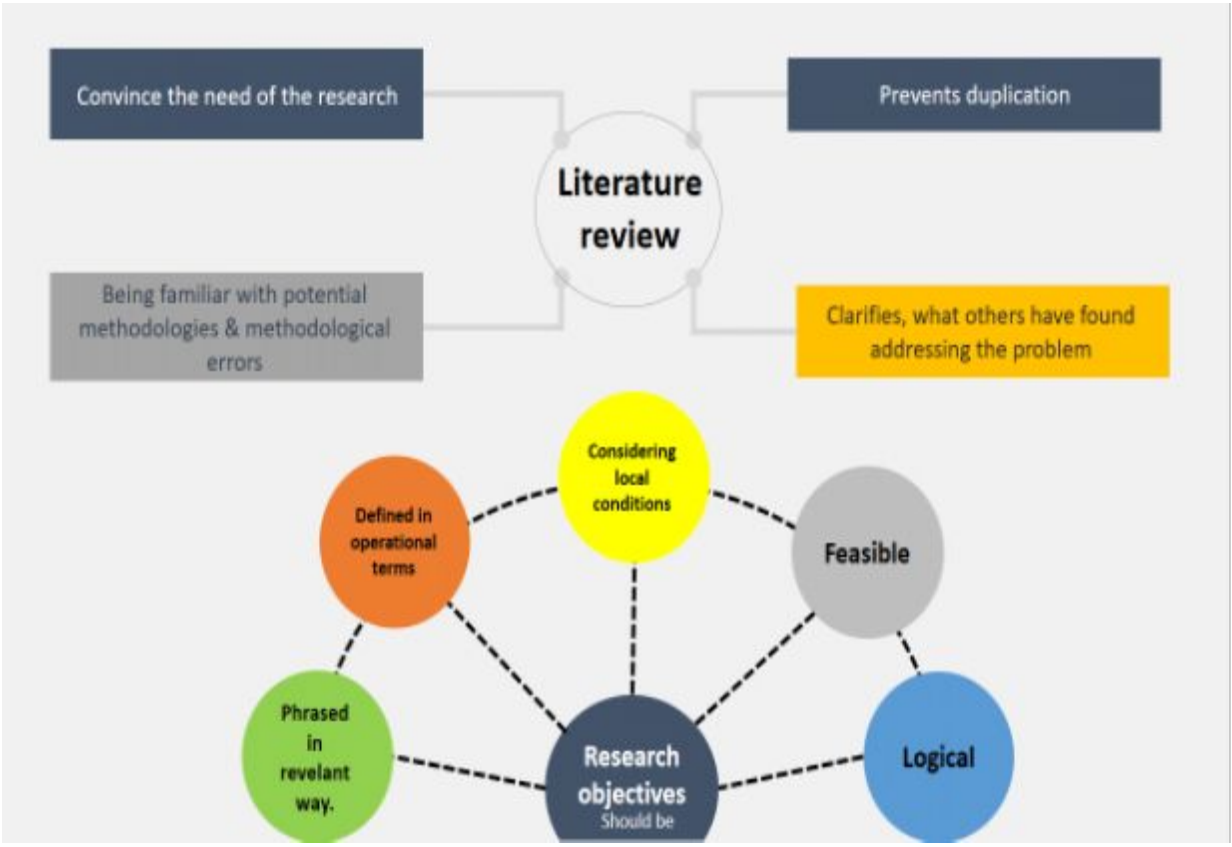
Editing file

Feedback link


SUMMARY
WHY A PROTOCOL?
Clarify the research question
Compile existing knowledge
Apply for funding
Formulate a hypothesis and objectives
Decide about a study design
To have a guideline and tool
Clarify ethical considerations
How to have a good protocol?
Provide enough detail, so others can do the study.
Feasible to set-up for the study
Answering the research questions & achieving the study objective.
Basic contents
Bibliography
Budget
Introduction
Objectives
Methodology
Plan of analysis
Ethical considerations


Literature review
Convince the need of the research
Prevents duplication
Being familiar with potential methodologies & methodological errors
Clarifies, what others have found addressing the problem
Research objectives
Should be
Considering local conditions
Defined in operational terms
Feasible
Phrased in revelant way.
Logical

What is research?

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

Why a protocol?

1. To clarify the research question
2. To compile existing knowledge
3. To formulate a hypothesis and objectives
4. To decide about a study design
5. To clarify ethical considerations
6. To apply for funding
7. 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? are you able to do it in your area or hospital?
- Does it provide enough detail (methodology) that can allow another investigator to do the study and arrive at comparable conclusions?

Basic content of the protocol:

The content of research protocols might vary according the content and context of the study

❖ Principal components:

- Introduction/rationale of the study. justification : why your research is important?
- Objectives/hypotheses
- Methodology. like study design, study subject, and analysis
- Plan of analysis
- Timeline. how much time you need for every step
- Ethical considerations
- Budget. you have to take a consent for it
- Bibliography. references

Title of a research project: - make sure it's catchy and interesting .

- (must be) Accurate, short, concise.
- Descriptive: should make the main objective clear, should mention the target population.
- Key words: should contain key words for referencing : must be attractive

i.e. „TB in HIV – infected children" very vague and open

Better: „Incidence of TB in HIV- infected children in North Uganda 2017-2018'' all information are understandable + short .

Project summary: *(abstract)*

> why it's important ? لأن أي أحد يبي يقرأ البحث حيروح للسمري أول ويشوفه ، اذا ماكان جيد كفاية مارح يتعب نفسه يقرأ البحث

- 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 ***REMEMBER : no research is perfect ! You better state the problems yourself instead of getting someone else criticizing your research*****:**

-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?

you MUST read at least (30) articles .

يساعدك تعرف عن الأبحاث السابقة, ايش المشاكل الي واجهوها؟ ايش انجزوا؟ والأهم يساعدك على تجنب تكرار البحث ونتائجه.

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!

the more literature review the more good your research will be

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 "big data with simple objective lead to confusion analysis "
- 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

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:

Observational study	Interventional study
Cohort study either prospective or retrospective , will take a lecture about it	Clinical trial
Cross-sectional study	
Case – control study	
Ecological study	

- The decision on study design needs to be based on ethics, logistic consideration, economic aspects and scientific thoroughness.
  Relevance to your objectives
- The validity of the results including potential bias and confounding and the generalizability of the results needs to be a prime concern defining the study design.

–Clinical trial > Cohort study > Case - control study > Cross-sectional 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: <u>Measurement of observations</u>:

- Describe how, when and where the observations are made? Describe instruments used!
  - Questionaire (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)

How to calculate the BMI in detail

Methodology: <u>Subjects/ participants:</u>

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: <u>Sample size:</u>

- Sample size calculation is recommeded 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: <u>Ethics checklist</u>

- 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:* most jurnals follow this style
    - Numbered references
    - Continous referencing in text
- ❖ Make use of software
  - Reference Manager
  - Endnote software

Work plan:

Tasks:

Who?

When?

Where?

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					

Budget

The budget should be broken down by:

1. Items
   - Personnel
   - Consumables, equipment, supplies, communication, funds for patients, data processing
2. Budget justification
   - Jusitify the use of each item, considering the workplan of the study

Annexes

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

Common mistakes:

- Including too little detail about proposed studies and insufficient justification for the significance of the problem. Not giving much information
- Proposing far more work than can be reasonably done during the grant period. proposing a very big subject that couldn't be done in the giving time period.

Practical hints for funding proposals:

- Discuss research proposal with your collaborators well in advance
- Strictly follow guidelines for applicants
- Application deadlines are strict
- Demonstrate your expertise
- Be realistic about the time things take
- Ask your colleagues to read your proposal prior to submission
- No typographical or other errors!

Consider the job of the reviewer … "the doctor did not read it"

The reviewer…

- has an interest in ranking the applications in an unbiased, fair, scientifically rigorous way, giving the best scores to those grants that are most likely to contribute to our body of knowledge.
- may not be extremely familiar with all techniques. All parts of the grant must be clear and written in such a way that a non-expert can understand them.
- may not know the applicant personally. It is the job of the applicant to convince the reviewer.
- may not fully understand the significance of the research area without a clear, compelling argument presented in the application.
- is capable of understanding and interpreting preliminary data if well-presented.
- must read 10 to 15 applications in great detail and form an opinion about all of them.

The successful proposal is clear and precise, is easy to read, has a detailed experimental design section, and is free of typographical and other errors.

THE END