01

HOW TO DEVELOP A RESEARCH PROTOCOL

KSU COLLEGE OF MEDICINE
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ACKNOWLEDGMENTS

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Still RECRUITING, JOIN US!

REVIEWER

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LECTURE **OBJECTIVES**

By the end of this lecture, I am able to:

- Understand the different steps of a research protocol.
- Understand the importance of a research protocol.
- Develop a research protocol on my topic of interest.

RESEARCH

Definition

Answering a question, or solving a problem using a systematic collection, analysis and interpretation of data.

RESEARCH PROTOCOL

Definition

A document proposing a research project, consisting of a request for sponsorship.

Unlike proposals, *protocols* are detailed, consisting of a step-by-step guideline.

Components

Components of research protocols vary according to your study.

The *Anatomy* of research: What it's made of (Question, Sample, Variables.. etc.)

The *Physiology* of research: How it works (Measurements).

Click the linked-texts below for great, relevant resources:

1. Protocol Writing in Clinical Research.
2. Fifteen Common Mistakes Encountered in Clinical Research.
3. A Guide to Using Qualitative Research Methodology.
4. What Is the Meaning of Variables in Research?
5. How to Use EndNote for Windows.
6. How to Use EndNote for Macintosh.

Why a Protocol

- Clarify your research question.
- Formulate hypotheses and objectives.
- Decide a study design.
- Refer to as guideline and tool for the research.
- Compile existing knowledge.
- Clarify ethical considerations.
- Apply for funding.

A Good Protocol

- Answers research question(s), and achieves the study objective(s).
- Feasible on its particular set-up i.e. timeframe.
- Provides enough detail (methodology) allowing other investigators to adapt the study.
- Delivers comparable conclusions.

PROTOCOL TITLE

Definition

The name. It is where you summarize your main idea(s) with fewest words possible to describe the content and purpose of your research paper.

Good Title

- Catchy and interesting.
- Descriptive, clarifying the main objective(s).
- Inclusive of keywords (for referencing).
- Inclusive of the target population.
- Not too elaborative.
- Accurate, short, and concise.

✗ TB in HIV – infected children.

✓ Incidence of TB in HIV- infected children in North Uganda 2017-2018.

PROTOCOL SUMMARY

Definition

A summary of something is a short account of *it*, that gives main points, not details.

Good Summary

- Concise to one page (≈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

Definition

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'.

Logical Flow

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? Is there consensus? Is there controversy? Is there conclusive evidence?
3. **Possible solutions:** In what ways have solutions to the problem been attempted? What has been proposed? What are the results?
4. **Unanswered questions:** What remains to be answered? What areas have not been possible to understand, determine, verify, or test?
5. Based on the points you will mention above, you develop your **objectives.**

PROTOCOL LITERATURE REVIEW

Definition

A summary of previous research done on a topic.

Aims To

- Prevent duplication of work that was already done.
- Clarify what others already found.
- Familiarize writers with potential methodologies, and methodological errors.
- Determine what you are going to add.
- Convince the need of your research.

PROTOCOL JUSTIFICATIONS

Definition

A convincing statement for the need to do this research.

Answers

- 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?

PROTOCOL OBJECTIVES

Definition

Description of what you expect to achieve by a research.

Aim To

- Focus the study, narrow it down to essentials.
- Avoid the collection of unnecessary data.
- Derive specific objectives from a general objective.
- Solving the problem you identified.
- Organize the study in defined parts.

Good Objectives

- Three objectives; One primary objective, and up to two secondary objectives.
- Logical, feasible, and realistic.
- Relevant, phrased to clearly meet the purpose of the study.
- Defined in operational terms that can be measured.
- Stated in action verbs that illustrate their purpose:
  e.g. to determine, to compare, to verify, to calculate, to reduce, to describe.. etc.

PROTOCOL HYPOTHESES

Definition

Assumptions that you can prove or disprove by the end of your study.

- Describes the **relationship** between **independent variables** (e.g. risk factors) and **dependant variables** (e.g. outcome of predisposing to these risk factors).
- Determines the type of data to collect, and the type of analysis to conduct.

PROTOCOL METHODOLOGY

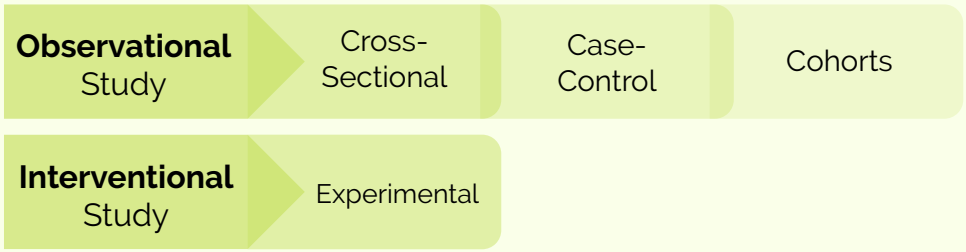
Definition

Techniques adopted in your research process to collect, assemble and evaluate data.

- proves or disproves **hypotheses**, using the right tools.
- Presents a detailed strategy on achieving **objectives**.

Study Designs

- **Deciding a study design is based on:** Ethics, logistic considerations, economic aspects, scientific thoroughness, and relevance to your objectives.
- **Prime concerns defining the study design are:** Validity of the results, including: potential bias, confounding, and generalizability.



Definition of Variables

Variables are anything that can affect, or change the results of a study. Every study has variables as these are needed in order to understand differences.

The definition of variables looks like:

Conceptual Definition	Operational Definition	Scale of Measurement
Age	Age at last birthday	Continuous: In months
Family Size	Number of family members	Discrete
Religion	As reported	Nominal

Measurement of Observation

- Attach the **questionnaire** to your protocol.
- Type of **interview**, and describe its structure.
- Refer to literature, personal knowledge, or describe in detail any **lab tests**.
- Describe gadgets and procedures any **clinical examinations**.
- Refer to specific literature and regulations for **interventions** (i.e. drug trials).

Participants (Subjects)

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

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

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 have to be set.

Data
Measurnment and Analysis

Based on objectives consider:

- Coding and type of variables.
- Appropriate Statistical tests.
- Analysis plan depending on type of variables.
- Style of presentation (e.g. tables, graphs.. etc.)

PROTOCOL ETHICAL CONSIDERATIONS

Why?

Ethics searches for reasons for acting or refraining from acting; for approving or not approving conduct; for believing or denying something about virtuous or vicious conduct or good or evil rules.

Informed Consent

Outline how, when and where will the participant be consented.

Information form should contain:

- Justification for research.
- Outline of study.
- A separate consent form is required.
- Responsibility (Who).
- Confidentiality (legal framework).

Ethics Checklist

- Potential questions regarding the ethics.
- Pros and cons of research design, subject selection, measurement, and outcome.
- Advantages and disadvantages of the subject involved.
- Physical, social and psychological implications of the research.
- Confidentiality.

PROTOCOL WORKPLAN

Why?

Split tasks into: Who, When, and Where.

PROTOCOL REFERENCES

Referencing Systems

Harvard Style: Name and publication year in text; Alphabetical bibliography.

E.g. Brown, D. (1998). Digital fortress. New York: St. Martin's Press.

Vancouver Style: Numbered references; Continuous referencing in text (more used).

E.g. Within the body of your article: (1), **then, within your citations:** 1. Digital fortress. New York: St. Martin's Press (USA): Brown, D; 1998.

Software Referencing

- Endnote.
- Reference manager.

PROTOCOL BUDGET

Broken Down By

- **Items:** Personnel, consumables, equipment, communication, data processing.. etc.
- **Justification:** Use of each item, considering the workplan.

PROTOCOL ANNEXUS

As In

Attachments:

Case record forms, questionnaires, and consent forms (in required languages).

FINAL POINTS

Practical Hints

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

Common Mistakes

- Insufficient details for proposed projects.
- Insufficient justification for the significance of problem.
- Proposing far more work than can be reasonably done during the grant period.

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.