



Dr Syeda Rumana Hoque
Department of Community Medicine

What is protocol?

The protocol is the detailed written plan of the study.



Components of a Research Protocol

- Title
- Protocol summary
- Introduction
- Rationale
- Research question / hypothesis
- Objectives
- Methodology- data management and analysis, ethical consideration
- Time schedule
- References
- Budget, application for grant

Title of the study

- The title should be smart (concise and informative)
- No abbreviation
- Example:
 - ❖ Utilization of ANC by the reproductive aged women
 - ❖ Utilization of ANC by the pregnant mother
 - ❖ Utilization of antenatal care by the pregnant mother at selective area of Gazipur district

Project summary

It should summarize all the elements of the protocol.

- Rationale
- Objectives
- Methods
- Populations
- Time frame
- Expected outcomes.

Investigators' detail

- All the investigators should be named and their contact details should be given.

Background

- ❖ It should answer the question of why and what.
- ❖ Why the research needs to be done.
- ❖ What will be its relevance.
- ❖ Any valuable and useful knowledge will be created or not.

Rationale

- ❖ Specifies the reasons for conducting the research.
- ❖ It should include a well documented statement of the need/problem that is the basis of the project.

Research Question

- It should be clear, unambiguous and specific
- It should be a single sentence in the form of a question

OR

Hypothesis where relevant.

Research Question (Example)

- What proportion of pregnant mothers had received antenatal care?

Hypothesis:

- Primigravida receive more antenatal care than multigravida.

Aims and Objectives

- Research objective may be stated as-
 - general objective
 - specific objective
 - ultimate objective

Aims and Objectives

- General objective-

It is a short statement that tells in a summary form what will be done during the study.

e.g. to determine the proportion of pregnant women receiving antenatal care.

Aims and Objectives

- Specific objective-

These are individual statements of the research question to fulfill the general objective. For example:

1. to determine the proportion of pregnant women receiving antenatal care.
2. to assess the number of antenatal visit paid by the respondents
3. to explore the factors for not attending antenatal visit
4. to assess the socio demographic status of the respondents

Methodology

It is the most important part of the protocol.

It should include information on-

- ✓ Research design
- ✓ Place of study
- ✓ Study population
- ✓ Sample size
- ✓ Sampling technique
- ✓ Research instrument
- ✓ Method of data collection
- ✓ Quality control of data
- ✓ Data processing and analysis
- ✓ Ethical consideration

Method of data collection

Procedure should be in detail specially where any intervention or laboratory procedure is needed.

Data management and analysis

- The protocol should provide information on how the data will be managed, including data handling and coding for computer analysis, monitoring and verification.
- The statistical methods used for the analysis of data should be clearly outlined.

Quality control of data

- Pretesting
- Repeated check for any omission/error
- Standardize equipment
- Including good clinical practice (GCP), follow up by clinical monitor, data safety monitoring board(DSMB), data management etc,

Ethical consideration

- An ethical committee permission is necessary for a research proposal.
- The protocol should have a description of ethical considerations relating to the study.
- It should also include informed consent from the research participants (the informed consent process).

Time frame

- The protocol should specify the time that each phase of the project is likely to take, along with a detailed month by month timeline for each activity to be undertaken.

References

- References should be formatted according to the guideline of the concerned institution where the protocol is to be submitted.

Budget

- This should include a detailed commodity-wise and service-wise breakdown of the requested fund.

THANK
YOU

