

Research Article

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Introduction

- Initial step in designing a study is the preparation of a written document that describes the proposed study in detail.
- Many points need to be addressed in a stepwise fashion.
- List of questions to serve as a guideline.

General Considerations

- Pages.
- Characters per line.
- Annexure.

Basic Outline of a Research Protocol

- Only guidelines to facilitate investigator's task.
- Not necessarily be applied rigidly.
- Depends on type of study and methodological approach.

Title of the Research Project

- Short, accurate and concise.
- Clear central objectives.
- "Keywords".
- Preview of the protocol.
- What population or universe?

Project Summary (Abstract)

- Clear idea about central question.
- Specify the hypothesis and research objectives.
- Methods and procedures.

Statement of the Problem

- Scientific justifications.
- Empirical references.
- Specify gaps in existing knowledge / controversies and non-conclusive evidence.

Logical Sequence for Presenting the Statement

Magnitude, frequency and distribution.

Geographical areas and population groups.

Ethic and gender considerations.

Probable cause of problem :

- Current knowledge
- Consensus
- Controversies etc

Possible solutions

Unanswered questions

Convincing Argument

Justification and Use of Results

- Final Objectives, Applicability and Strategy

Justification should answer the following: -

- Priorities of region / country.
- Knowledge and information.
- Purpose it will serve.
- Dissemination of results.
- Usefulness of results and beneficiaries.

Theoretical Framework (Argumentation, Possible Answers, Hypothesis)

- Derived from the statement of problem.
- Involves establishment of relationships.
- Possible answers? Assumptions? Hypothesis.
- Considers The "Rounds" That Support the Central Question of the Study.

Research Objectives

- Intellectual activities that the investigator will perform throughout the research process.
- General and Specific.
- General - Should specify what kind of knowledge the study is expected to obtain.
- Specific - These disaggregate and follow logically from the general objective. Is preliminary view of the research design?

Methodology

- Explains the procedures that will be used to achieve the objectives.

What is expected?

Operational definition of variables (Quantitative/Qualitative).

Type of study and general design:

On the basis of proposed objectives.

Availability of resources.

Ethical considerations.

Mechanisms used to reduce or eliminate threats to the validity of the results (Confounding Factors).

Population.

Sample selection and observation.

Unit of 'Analysis and Observation'.

Selection criterion.

Proposed interventions

Data collection procedures, Instruments used and methods for data quality control:

- Instruments
- Questionnaires
- Interview guides
- Registration Forms etc
- **Ethical considerations:**
- Known benefits or risks.
- Communication mode.
- Incentive and treatment.
- Confidentiality.
- Informed consent.
- Synopsis on reporting and delivering of research findings.
- Indicate justification of inclusion / non-inclusion.
- Appropriate balance of two sexes.
- Institutional Ethical Committee Clearance - when studies involve human subjects
- Form.
- Informed Consent.
- Prior approval.

Plan for Analysis of Results

- What is expected?

Methods and models of Data analysis according to types of variables:

- How variables will be measured?
- How to prevent the variables?
- Statistical techniques / tests.

Preliminary Scheme for tabulating the data.

Software package.

Bibliographic References

- As latest as possible.
- Few historical / evolutionary.
- How to write.

Timetable

Budget

Total anticipated.

Financial year wise.

Time frame of utilization.

Distribution:

Equipment.

Chemical / Reagents.

Accessories.

Stationary

Contingencies etc

Annexes

- Data Collection instruments.
- Elaboration on methods and procedures to be used.

Research Projects in Armed Forces

- AFMRC
- Departmental
- ICMR
- WHO Sponsored

Considerations

- Service oriented.
- Feasible.
- Time Bound (PDC).
- Budgetary aspects.
- Worker / Co-workers.
- Outcome beneficial to service.
- Multidisciplinary.
- Multicentric.
- Statistical Analysis.
- Approval of DFR.
- Final Report.
- Recognition.
- Awards / Prizes.