

## FORMULATION OF HEALTH RESEARCH PROTOCOL – A STEP BY STEP DESCRIPTION

*Sanjay Singh<sup>1</sup>, P Suganthi<sup>1</sup>, Jameel Ahmed<sup>1</sup> & VK Chadha<sup>2</sup>*

### SUMMARY

This article attempts to provide the researchers, the various steps involved in formulating a health research protocol. In population based health research, majority of the studies conducted are observational rather than experimental. Therefore, it is essential to elaborate and follow a research protocol as in laboratory research. Doing this will increase the likelihood that the conclusions drawn from the research will be scientifically sound.

The first step in developing a protocol is the selection of an appropriate research topic. The protocol should explain the study in terms of answers to the study questions viz. Why?, how?, who?, what? and so what?. Protocol should start with an introduction followed by, objectives, study design, methods, project management, strengths and limitations, ethical considerations, expected outcome, budget summary, references and annexures. In annexure part, study formats/questionnaires, budget details and curriculum – vitae of chief investigator can be given. Once, a protocol is prepared a summary of it should be placed at the top of the protocol i.e. before introduction part. At the end of the article some important tips are described to be considered while formulating a protocol.

**Key words :** Health research, protocol, study questions, study design, project -management, ethical consideration.

### INTRODUCTION

Research is a systematic process of collection, analysis and interpretation of data for generating new knowledge or to answer certain questions. Research involves various people working together: these include the Investigators, laboratory and field staff, the statisticians, the institution in which the research is carried out, those who provide the finances, the participants or study subjects and their community.

#### Why health research ?

We do health research for achieving two major objectives viz., (i) to generate new knowledge and technologies to deal with major unresolved health problems; this could be called **basic research**. And (ii) to identify priority problems and to design and evaluate policies and programmes that will use optimal resources for maximizing benefit; this could be called **applied research**.

Operational research is one type of applied research that focuses on improving accessibility, acceptance, quality and sustainability of services

Besides serving these two major purposes research can also be viewed as a tool for development of human resources for health because research process stimulates researchers to think logically and provokes them to create innovative health interventions for overcoming the health problems.

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1. Field Investigator, 2. Senior Epidemiologist, National Tuberculosis Institute, 8 Bellary Road, Bangalore - 560 003, Fax: 080-23440952, E-mail: ntiindia@blr.vsnl.net.in

## Research protocols

In population based health research, despite the fact that many of the studies are observational rather than experimental, it remains essential to elaborate and follow a research protocol for the same reason as in laboratory research. Doing so will increase the likelihood that the conclusions drawn from the research are scientifically sound.

The first step before embarking and developing a detailed protocol is to select a research topic. The topic should be able to stand alone as an explanation of the study. In doing so we need to understand prevailing operational realities and how to work within their limits. The protocol should explain the study in terms of answers to the following questions<sup>1</sup>:

◆ **WHY ?** Sets out the study questions and

the relevant background information: that why we should embark on this particular research problem.

- ◆ **HOW ?** Describes the study design and the rational for choosing it. Also describes Instruments / techniques to be used
- ◆ **WHO ?** Defines the targets and the study population and sample size.
- ◆ **WHAT?** Identifies the variables to be measured and outcomes to be analyzed.
- ◆ **SO WHAT?** Comments on the expected significance of results and contribution to knowledge.

### Elements of research protocol

While formulating a scientifically sound health research protocol, following elements/ steps

1. **Protocol summary**
2. **Introduction**
  - *Study questions*
  - *Rationales and Previous knowledge on the subject*
3. **Objectives**
4. **Design and methods**
  - *Study design*
  - *Study population*
  - *Sample size and sampling*
  - *Study subject : selection, definitions*
  - *Study questionnaires, formats*
  - *Data collection methods*
  - *Data management and statistical analysis*
5. **Project Management**
  - *Personnel*
  - *Action - plan*
6. **Strengths and limitations**
7. **Ethical considerations**
8. **Expected outcome**
9. **Budget summary**
10. **References**
11. **Annexure**
  - *Study formats*
  - *Budget details*
  - *Curriculum – vitae of Chief Investigator and Co-investigator*

should be taken into consideration<sup>1,2</sup>

## 1. PROTOCOL SUMMARY

Summary should be concise but must be sufficient to orient the reader to the main purpose of the study, how it would be conducted and its expected benefits. It is a sketch plan of the study, which provides quick details and general plan of the study before getting into the main document. *It is placed before the protocol, but is often written after the protocol itself is completed.*

## 2. INTRODUCTION

### ***Study question***

Protocol should start with a clear and precise formulation of the research question. It may be a good practice to write this in the form of a question and not as a statement. While formulating research question, its relevance to public health, feasibility of conducting the study to answer the question and likelihood of implementation of the findings must be kept in mind. The more precise the question, the more likely it is that research will provide new knowledge. Therefore the question format requires greater precision and lead to a logical approach to the research topic.

### ***Rationale and previous knowledge on the subject***

The purpose of this section is to state how the research question arose from current knowledge about the subject. The progression of your ideas needs to be set out in a logical sequence. We must be very concise; include key references, not a complete review of the literature. The following points must be taken into consideration while dealing with this section:

- ◆ Discuss the importance of the topic.
- ◆ Review the relevant literature and current knowledge (including deficiencies in knowledge that make the study worth

doing).

- ◆ Describe any results you have already obtained in the area of the proposed study.
- ◆ Indicate how the research question has emerged and fits logically.
- ◆ Outline your approach to address the research question.
- ◆ Explain how your study will benefit the community.

## 3. OBJECTIVES

The study objectives emerge from the study questions. It indicates the specific approach towards answering the study question and is precise and measurable. Objectives must depict why we want to carry out the research and what we are going to achieve from the study? The objectives should be Specific, Measurable, Achievable, Relevant and Time based (SMART objectives).

## 4. DESIGN AND METHODS

### ***Study design***

This section should state the selected design of the study. The study designs can be classified into following:

- (i) Cross-sectional study
- (ii) Cohort study
- (iii) Case-control study
- (iv) Experimental/intervention study.

Explain why a particular study design has been chosen in preference to others.

### ***Study population***

This section defines the group in which the study will be carried out and to whom will the results refer – Geography / age-group/ epidemiological group.

### ***Sample size and sampling***

This section describes the sample size estimation and techniques to be used for the

sampling.

### ***Study subject: selection, definitions***

This section should explain the following points:

- ◆ How many subjects will be selected, where and why?
- ◆ Define eligibility, inclusion and exclusion criteria
- ◆ Mechanism of selection.
- ◆ Estimation of the number of potentially eligible subjects.
- ◆ Feasibility of selecting the required number of subjects and estimate the proportion that will agree to participate.

### ***Study questionnaires & formats***

Study questionnaires or data collection formats should be designed in such a manner that it will include all the required information in a systematic manner with a brief introduction on the study formats or questionnaires. All the study formats or questionnaires should be placed as annexures.

### ***Data collection methods***

It is essential to state how the data will be collected to determine the outcome of the study. Quality control procedures should also be specified. It should include the following points:

- ◆ Definition of all terms
- ◆ Pilot testing for methods and instruments
- ◆ The validity and reliability of the definitions proposed
- ◆ The limitation of the measurement tools and definition proposed

### ***Data management and statistical analysis***

This section should describe the following:

- ◆ Procedures for coding and entering data

into computer files

- ◆ Measures to ensure the completeness and accuracy of the information
- ◆ Examples of how the results will be displayed and comparisons made
- ◆ Statistical tests to be carried out in order to test each of the stated hypotheses
- ◆ Appropriate references for the statistical tests and computer programme to be used

## **5. PROJECT MANAGEMENT**

### ***Personnel***

This section will identify the manpower required to carry out the study and define their tasks. It will justify the personnel proposed in terms of the tasks and the amount of time required. It should also specify the responsibility of each staff member including the requirement of training. For standardization of work plan the personnel involved in data collection or other tasks should be adequately trained and evaluated before their deployment in the study.

### ***Action – plan***

Action-plan or the time schedule will set out the anticipated time required for each phase of the study, including:

- ◆ Pilot testing
- ◆ Recruiting of subjects
- ◆ Preparation of study questionnaires or formats
- ◆ Logistics including personnel and training
- ◆ Data collection
- ◆ Follow-up procedures
- ◆ Data scrutiny and statistical analysis
- ◆ Reporting procedures

## **6. STRENGTHS AND LIMITATIONS**

It is important to include in this section the

possible criticisms of your design & methods and provide reasons why you think the limitations imposed by your choices are not the serious ones. Similarly, it is useful to identify important aspects of the specific protocol that are particularly strong and worthy of financial support.

## 7. ETHICAL CONSIDERATION

In this section it is important to specify the ethical issues involved in the study like benefits of the study procedures, hazards, responsibility of injury, voluntary consent etc. This session will help ethical committee to scrutinize the protocol considering all the ethical issues involved before approving it.

## 8. EXPECTED OUTCOME

This section restates the justification for the study in terms of the anticipated results. It will specify the following points:

- ◆ The implications of the potential results
- ◆ How the results of the study may be useful to the policy makers, community at large and for future research

## 9. BUDGET SUMMARY

A brief outline of the budget requirement showing head-wise expenditure for the study should be given in this session. e.g. manpower, logistics, transportation etc. A detailed budget estimate showing all the expenditures under various heads can be placed in annexure.

## 10. REFERENCES

In this section list of the various references quoted while formulating protocol may be listed in a sequential manner.

## 11. ANNEXURES

### ***Study formats/questionnaires***

All the formats/questionnaires that may be used in the study should be placed in the annexure

in a systematic manner.

### ***Budget details***

Each item of expenditure expected for the conduct of the study must be specified along with a justification.

### ***Investigator: role and curriculum – vitae***

This section should describe role of each investigator in the study, and state clearly who is responsible for each component of the study. The curriculum – vitae should provide a clear description of the qualification and experience of the investigators, including training, academic degrees or certificates, research experience and scientific publications.

## IMPORTANT TIPS

The following information is important and must be taken into account before starting to write a research protocol<sup>3</sup>:

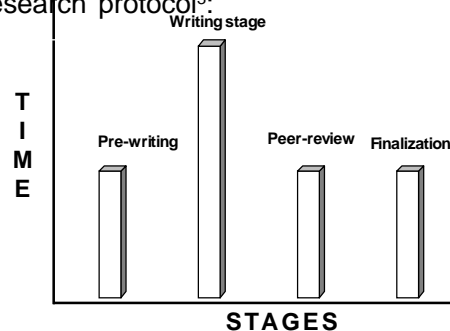


Figure: Steps in protocol writing

1. Planning is essential when preparing a research proposal. On an average, 2 - 3 months will be needed to prepare and clear a proposal.
2. To be successful in mobilizing resources, it is important to study the sectoral funding policy and procedures of the funding institution.
3. During pre-writing stage, desk research should be conducted; the available health

and demographic statistics must be gathered and relevant research results consulted.

4. Knowledge should be gathered about the partners, their strength and their weaknesses, and their tasks and responsibilities within the proposal should be adapted accordingly.
5. Draft protocol must be peer-reviewed and finalization may be done only after incorporating the suggestions obtained.

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