Clinical Research and Reports
2024 Volume 2, Issue 4
DOI: 10.59657/2995-6064.brs.24.025

BRS BioRes Scientia
Value your Research

Opinion Article

Open Access

Protocol Writing in Clinical Research

Sakshi Ambilwade

Sandip Institute of Pharmaceutical Science, Nashik, Maharashtra, India.

Abstract

Protocol is document that describe the scientific planning for conducting the research. Writing a research protocol is one of the most challenging tasks for the researcher. In this article we are discussed about the most important steps for writing the research protocol. Protocol helps to describe the study objectives, methods, design, statistical consideration, quality of data. Writing a protocol allows the researcher to plan and review the project steps. It also provides time and budget estimation.

Keywords: researcher; protocol; study design

Introduction

Protocol is defined as per ICH- GCP – A document that describe the objective(s), design, methodology, statistical consideration, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. It's an important document which is provided by the study investigator for conducting clinical trial as per describe in a rationale, methods and plans for study [1.2].

What is a protocol?

Clinical research is conducted according to the plan or idea (a protocol) that contain all the study related information. Protocol describes the participants eligibility, study duration and study intervention, medications and relevant testing. The protocol provides the guidelines for conducting the clinical trial. Research member check the health of the participant regularly to confirm the safety and effectiveness or efficacy of the trial study [2].

Why the Clinical Trial Protocol is Needed?

Protocol is an important aspect to perform a clinical trial. The clearly written, transparent and well detailed protocol helps to enable the trial in time and comprehensive assessment of the clinical trial [11].

It helps to ensure the safety and efficacy for all the subject participants

It gives a proposed study plan

It helps to manage the trial and follow by study investigator

It required to get ethical approval form ethics committee for conducting a trial.

Purpose of the Research Proposal Aims

To raise questions for research and clarify their importance.

To collect the existing knowledge and discuss the efforts of the other researcher who have worked on that related question. i.e., literature review

To formulate the hypothesis and research objective.

To clarify the ethical consideration.

To suggest the methodology required for solving the question and achieve the objective.

To discuss the requirements and limitations for achieving the objective.

Writing The Protocol

Protocol writing allow researcher to review and evaluate already published literature on new, interested topic, plan and review the steps of project and guide throughout the investigation.

Table: The components of the protocol [1,2].

Components
1) Title of the study
2) Administrative details
3) Project summary
4) Introduction to the research topic, background (Literature review)
5) Preliminary studies
6) Study objectives and/or questions. Statement of the problem.
7) Methodology: Study design, study population and methods of recruitment, variables list, sample size, methods of data collection, data collection tools, plan of analysis (analysis of data)
8) Project management: Work plan (Timeline -proposed schedule)
9) Strengths and limitations of the study
10) Issues for ethical review and approvals

1. Title of the study

Title of the proposal should be accurate, clear, short, consice, and identify.

What is the study about, who are the targets, when it is launched, where is setting of study?

Keep the title within 12-15 words. Title should convey the idea about the research [4].

2. Administrative details

Content page

Signature page

Contact details

3. Project summary

Summary should be consice, distinctive and should include the all-essential information pf the protocol.

4. Introduction

Introduction or background of the project is to be consice. Attention should br drawn to positive and study limitation when writing review. Research question should be described concisely and precisely on the basis of project designing. Review includes recent publication in field and topic of research selected after completing literature review and finding some gaps in that [3].

5. Study objectives

Aim should be stated as explicitly. Aims should confined the intention of project and arise from literature review. Aim helps to state the goals need to achieve. The objective should be SMART. i.e., Specific, Measurable, Achievable, Relevant, Time-based.

6. Methods and Materials

it should describe the detail about 'Where', 'Who', 'How' the research will be conducted. A suitable study design and methodology chose for the research to achieve the research aim. It explains the study design: single center or multicentric trials, retrospective or prospective study, controlled or uncontrolled clinical trial design, ob servational and experimental design, randomized and non-randomized study design. Explanation is required for why this study design is chosen for conducting the trial. Clearly define the inclusion and exclusion criteria for the study population. Calculate the sample size. Describe the screening process for recruitment process [7].

7. Data collection methods, used

Data collection tools are

Questionnaire

Retrospective data

Clinical examinations

Description of instrument use for data collection

Interview

Laboratory test

8. Project management

Work plan is helpful for outline the activities of research carried out on all phases according to time schedule [9].

9. Strength and limitations:

study's strength and limitation are an important for i.e., what study can achieve or cannot achieve that is important. It's helpful to avoid wastage of resources [5].

10. Ethical considerations

It indicates that the procedure follows according to the Declaration of Helsinki. Issue approval from ethical review is mandatory unless study not start due to ethics committee approval [6].

11. Budgeting

outline the requirement of budget for study expenditure- manpower, instruments, laboratory tests, transportation, equipment, cost of the drug [9].

12. Reference system: Referencing is the method for recognizing that information is taken from other researcher's work. Proper citation uses for the information [11].

13. Annexure

The following annexure added at the end of the clinical research protocol:

1. Informed consent form
2. Letters from ethics committee
3. Case record forms
4. Budget detail
5. Curriculum vitae of investigator and study team members
6. Study questionnaire

Conclusion

Preparation of study protocol is considered as a most difficult phase of conducting research. Protocol is a short document that contain the summary of the project. Protocol is considered successful when it is clear, easy to read. Accurate and free from error.

Reference

1. WMA. (2012). Declaration of Helsinki-Ethical Principles for Medical Research Involving Hurnan Subjects. *World Medical Association*.
2. (2014). Guidelines for writing a research protocol.
3. Bhandari M. Devereaux P, Monteri V. (2004). Cina Tandan VGuyatt G. Evidence-based surgery working group. Users guide to the surgical literature: How to use a systematic iterature review and meta-analysis. *Canadian journal of surgery*, 47(1):60-67
4. Al-lundi A, Sakka. (2016). Protocol Writing in Clinical Research. *Journal of Clinical and Diagnostic Research*, 10(11):10-13
5. (2014). Study designs in medical research.
6. (2013). Citing References and Avoiding Plagiarism. *Library Services, University College London*.
7. Smith MC. (1984). Research methodology: Epistemologic considerations. *Image J Nurs Sch*, 16(2):42-46
8. Smith MC. Research methodology: Epistemologic considerations. *Image J Nurs Sch*, 16(2):42-46.
9. (2014). Guidelines for writing a research protocol. *Pan American Health Organization*.
10. Eaton K, Santini A. (2011). An introduction to research for primary dental care clinicians. Part 3: Stage 5. Writing a protocol. *Prim Dent Care*, 18(2):91-94.
11. Singer PA. (2001). Beyond Helsinki: A vision for global health ethics. *Br Med J*, 322(7289):747-748.

Cite this article: Ambilwade S. (2024). Protocol Writing in Clinical Research, *Clinical Research and Reports*, BioRes Scientia Publishers. 2(4):1-3. DOI: 10.59657/2995-6064.brs.24.025

Article History: **Received:** March 22, 2024 |**Accepted:** April 15, 2024 | **Published:** April 30, 2024