Research Protocol

What Is Research Protocol?

The research protocol is a document that describes the background, rationale, objective(s), design, methodology, statistical considerations and organization of a clinical trial. It is a document that outlines the clinical research study plan. Furthermore, the research protocol should be designed to provide a satisfactory answer to the research question. The protocol in effect is the cookbook for conducting your study

Why Is Research Protocol Important?

In clinical research, the research protocol is of paramount importance. It forms the basis of a clinical investigation. It ensures the safety of the clinical trial subjects and integrity of the data collected. Serving as a binding document, the research protocol states what you are—and you are not—allowed to study as part of the trial. Furthermore, it is also considered to be the most important document in your application with your Institution's Review Board (IRB).

It is written with the contributions and inputs from a medical expert, a statistician, pharmacokinetics expert, the clinical research coordinator, and the project manager to ensure all aspects of the study are covered in the final document.

Is Research Protocol Same As Research Proposal?

Often misinterpreted, research protocol is not similar to research proposal. Here are some significant points of difference between a research protocol and a research proposal:

Research Proposal	Research Protocol
A research proposal is written to persuade the grant committee, university department, instructors, etc.	A research protocol is written to detail a clinical study's plan to meet specified ethical norms for participating subjects.
It is a plan to obtain funding or conduct research.	It is meant to clearly provide an overview of a proposed study to satisfy an organization's guidelines for protecting the safety of subjects.
Research proposals are submitted to funding bodies	Research protocols are submitted to Institutional Review Boards (IRBs) within universities and research centers.

What Are the Elements/Sections of a Research Protocol?

According to Good Clinical Practice guidelines laid by WHO, a research protocol should include the following:

1. General Information

- Protocol title, protocol identifying number (if any), and date.
- Name and address of the funder.
- Name(s) and contact details of the investigator(s) responsible for conducting the research, the research site(s).
- Responsibilities of each investigator.
- Name(s) and address(es) of the clinical laboratory(ies), other medical and/or technical department(s) and/or institutions involved in the research.

2. Rationale & Background Information

- The rationale and background information provides specific reasons for conducting the research in light of pertinent knowledge about the research topic.
- It is a statement that includes the problem that is the basis of the project, the cause of the research problem, and its possible solutions.
- It should be supported with a brief description of the most relevant literatures published on the research topic.

3. Study Objectives

- The study objectives mentioned in the research proposal states what the investigators hope to accomplish. The research is planned based on this section.
- The research proposal objectives should be simple, clear, specific, and stated prior to conducting the research.
- It could be divided into primary and secondary objectives based on their relativity to the research problem and its solution.

4. Study Design

- The study design justifies the scientific integrity and credibility of the research study.
- The study design should include information on the type of study, the research population or the sampling frame, participation criteria (inclusion, exclusion, and withdrawal), and the expected duration of the study.

5. Methodology

- The methodology section is the most critical section of the research protocol.
- It should include detailed information on the interventions to be made, procedures to be used, measurements to be taken,

observations to be made, laboratory investigations to be done, etc.
- The methodology should be standardized and clearly defined if multiple sites are engaged in a specified protocol.

6. Safety Considerations

- The safety of participants is a top-tier priority while conducting clinical research.
- Safety aspects of the research should be scrutinized and provided in the research protocol.

7. Follow-up

- The research protocol clearly indicate of what follow up will be provided to the participating subjects.
- It must also include the duration of the follow-up.

8. Data Management and Statistical Analysis

- The research protocol should include information on how the data will be managed, including data handling and coding for computer analysis, monitoring and verification.
- It should clearly outline the statistical methods proposed to be used for the analysis of data.
- For qualitative approaches, specify in detail how the data will be analysed.

9. Quality Assurance

- The research protocol should clearly describe the quality control and quality assurance system.
- These include GCP, follow up by clinical monitors, DSMB, data management, etc.

10. Expected Outcomes of the Study

- This section indicates how the study will contribute to the advancement of current knowledge, how the results will be utilized beyond publications.
- It must mention how the study will affect health care, health systems, or health policies.

11. Dissemination of Results and Publication Policy

- The research protocol should specify not only how the results will be disseminated in the scientific media, but also to the community and/or the participants, the policy makers, etc.
- The publication policy should be clearly discussed as to who will be mentioned as contributors, who will be acknowledged, etc.

12. Duration of the Project

- The protocol should clearly mention the time likely to be taken for completion of each phase of the project.
- Furthermore a detailed timeline for each activity to be undertaken should also be provided.

13. Anticipated Problems

- The investigators may face some difficulties while conducting the clinical research. This section must include all anticipated problems in successfully completing their projects.
- Furthermore, it should also provide possible solutions to deal with these difficulties.

14. Project Management

- This section includes detailed specifications of the role and responsibility of each investigator of the team.
- Everyone involved in the research project must be mentioned here along with the specific duties they have performed in completing the research.

15. Ethics

- The research protocol should also describe the ethical considerations relating to the study.
- It should not only be limited to providing ethics approval, but also the issues that are likely to raise ethical concerns.
- Additionally, the ethics section must also describe how the investigator(s) plan to obtain informed consent from the research participants.

16. Budget

- This section should include a detailed commodity-wise and service-wise breakdown of the requested funds.
- It should also include justification of utilization of each listed item.

17. Supplementary Support for the Project

- This section should include information about the received funding and other anticipated funding for the specific project.

18. Collaboration With Other Researchers or Institutions

- Every researcher or institute that has been a part of the research project must be mentioned in detail in this section of the research protocol.

19. Curriculum Vitae of All Investigators

- The CVs of the principal investigator along with all the co-investigators should be attached with the research protocol.
- Ideally, each CV should be limited to one page only, unless a full-length CV is requested.

20. Other Research Activities of Investigators

- A list of all current research projects being conducted by all investigators must be listed here.

21. References

- All relevant references should be mentioned and cited accurately in this section to avoid plagiarism.

How Do You Write a Research Protocol? (Research Protocol Example)

Main Investigator

Name

Address

Phone/Fax

E-mail

Number of Involved Centers (for multi-centric studies)

Indicate the reference center

Title of the Study

Protocol ID (acronym)

Keywords (up to 7 specific keywords)

Rationale

Study Design

Mono-centric/multi-centric

Perspective/retrospective

Controlled/uncontrolled

Open-label/single-blinded or double-blinded

Randomized/non-randomized

n parallel branches/n overlapped branches

Experimental/observational

Objectives

Endpoints (main primary and secondary endpoints to be listed)

Expected Results

Analyzed Criteria

Main variables/endpoints of the primary analysis

Main variables/endpoints of the secondary analysis

Safety variables

Health Economy (if applicable)

Visits and Examinations

Therapeutic plan and goals

Visits/controls schedule (also with graphics)

Comparison to treatment products (if applicable)

Dose and dosage for the study duration (if applicable)

Formulation and power of the studied drugs (if applicable)

Method of administration of the studied drugs (if applicable)

Informed Consent

Study Population

Short description of the main inclusion, exclusion, and withdrawal criteria

Sample Size

Estimated Duration of the Study

Safety Advisory

Classification Needed

Requested Funds

Additional Features (based on study objectives)

References

Click Here to Download the Research Protocol Example/Template

Be prepared to conduct your clinical research by writing a detailed research protocol. It is as easy as mentioned in this article. Follow the aforementioned path and write an impactful research protocol. All the best!