

Protocol and Amendment:

A protocol is a document that explains the purpose, design, methods, statistical plans, and organization of a trial. It usually also includes the background and reasons for the trial, though these may be provided in other referenced documents.

A protocol is a formal document that outlines how a trial is conducted. It ensures consistency, safety and scientific integrity across all sites and participants. The protocol acts as a roadmap for researchers and staff, showing them what to do at each stage of the study, right from planning, data collection and analysis

The protocol includes:

- The purpose of the study, explaining why the trial is being done
- Who can take part, specifying eligibility criteria
- How the trial is designed, including what treatments or interventions will be used
- The procedures and tests participants will undergo and when these will happen
- How data will be collected, managed and analyzed scientifically
- Measures to protect participant safety and ethical standards
- How the trial will be organized and overseen to ensure consistency across all sites

The protocol should include appropriate level of details necessary for the reader to be able to understand exactly what is needed to conduct the study.

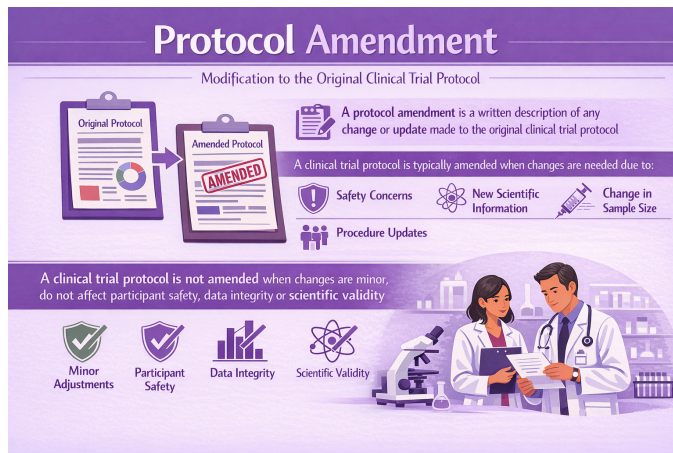
For example – blood pressure measurement should be described in more detail in protocol for a “**hypertension study**” where it is a primary efficacy parameter than in protocol for another disease area where blood pressure is assessed as a part of general assessment or safety check.

Key users of Protocol:

The clinical trial protocol is a vital document that guides every aspect of a study, right from start to finish. Various stakeholders use it as a reference to ensure the trial is ethical, scientifically sound and compliant with regulations. Each user plays a distinct role in maintaining the integrity and success of the trial. The following details describe the main stakeholders who refer to the clinical trial protocol and their reasons:

- **Principal Investigator:** To know exactly how to run the study safely, fairly and correctly
- **Clinical Research Coordinators:** To manage day to day tasks like patient visits, data entry and sample collection
- **Sponsor:** To monitor progress and ensure the trial is being conducted as planned
- **Monitors / Clinical Research Associates :** To check if sites are following the protocol and that data is accurate, consistent, compliant
- **Data Managers:** To understand how data should be collected, managed and verified to ensure accuracy, consistency, and compliance throughout the study
- **Statisticians:** To apply the correct analysis methods and interpret results based on the study's design and objectives

Protocol Amendment



A protocol amendment is a written description of any change or update made to the original clinical trial protocol. A clinical trial protocol is typically amended when changes are needed due to safety concerns, availability of new scientific information, procedure updates or there is a change in the sample size, that is the number of

participants in the study is changed. A clinical trial protocol is not amended when changes are minor, do not affect participant safety, data integrity or scientific validity