Protocol Development

Clinical Trial Protocol Development

Every clinical investigation begins with the development of a clinical protocol. A research protocol is a document that describes how a clinical trial will be conducted (background, rationale, objectives, design, methodology, statistical considerations, and organization of a clinical research project), and the methods used to ensure the safety of the trial subjects and integrity of the data collected.

- Title Page (General Information)
- Background Information
- Objectives/Purpose
- Study Design
- Selection and Exclusion of Subjects
- Treatment of Subjects
- Assessment of Efficacy
- Assessment of Safety
- Adverse Events
- Discontinuation of the Study
- Statistics
- Quality Control and Assurance
- Ethics
- Data and Safety Monitoring Plan
- Data handling and Recordkeeping
- Publication Policy
- Project Timetable/Flowchart
- References
- Supplements/Appendices

The NIH provides many resources for protocol development to assist investigators in writing and developing clinical research protocols that are in compliance with regulatory/GCP requirements. Some NIH institutes have a mandatory requirement for using their protocol template.

Study Design consultation and assistance are available at UCLA. Please contact the CTSI study design team for more information

Please review the ICH-GCP Protocol Checklist for additional guidance.

Sample Protocol Templates and Resources:

- UCLA Protocol Template (investigator-initiated)
- UCLA Protocol Template (industry sponsor)
- UCLA Non-Therapeutic Protocol Template
- UCLA Data Bank Template
- NIDCR-Interventional Protocol Template (Drug, Device, Behavioral)
- NIAID Clinical Research Toolkit- Clinical Trials Protocol Templates
- NCI-CTEP Protocol Development Templates and Guidelines

- NIH Glossary of Common Clinical Research Terms

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