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**
- **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**
- **NINDS Glossary** of Clinical Research Terms

Last updated: 30 Oct 2017
Group 1
- Clinical Research Information Systems
- Clinical Research Business Partners

Group 2
- Office of Research Administration
- Jonsson Comprehensive Cancer Center

Group 3
- Office of Human Subjects Protection
- CareConnect Website

© 2016 The Regents of the University of California. All rights reserved.

Source URL: https://www.researchgo.ucla.edu/protocol-development