

Contents of a Clinical Trial Protocol (Example)

1. Title Page
2. Protocol Synopsis
3. Schedule of Assessments
4. Table of Contents
 - (a) List of Tables
 - (b) List of Figures
5. Introduction
 - (a) Background
 - (b) Study Rationale
6. Study Objectives
 - (a) Primary Objective
 - (b) Secondary Objectives
7. Study Endpoints
 - (a) Primary Endpoint
 - (b) Key Secondary Endpoints
 - (c) Other Secondary Endpoints
 - (d) Other Endpoints
8. Study Design
 - (a) Overview of Study Design
 - i. Screening
 - ii. Treatment Period
 - iii. Follow-up
 - iv. Early Discontinuation
 - v. Loss to Follow-up
 - vi. Data and Safety Monitoring Board
 - (b) Rationale for Study Design and Study Drug Regimens
 - i. Study Design
 - ii. Study Drug Dose and Duration
 - iii. Rationale for Study Assessments
9. Study Population
 - (a) Inclusion Criteria
 - (b) Exclusion Criteria
 - (c) Study Restrictions
 - (d) Prior and Concomitant Medications and Other Study Restrictions
 - i. Prohibited Medications
 - ii. Prior and Concomitant Medications
 - (e) Removal of Subjects
 - (f) Replacement of Subjects
10. Study Drug Administration and Management
 - (a) Preparation and Dispensing
 - (b) Administration
 - (c) Method of Assigning Subjects to Treatment Groups

- (d) Study Drug Interruption
 - (e) Dose Modification for Toxicity
 - (f) Packaging and Labeling
 - (g) Study Drug Supply, Storage, and Handling
 - (h) Drug Accountability
 - (i) Disposal, Return, or Retention of Unused Drug
 - (j) Compliance
 - (k) Blinding and Unblinding
 - i. Blinding
 - ii. Unblinding
11. Assessments
- (a) Timing of Assessments
 - (b) Informed Consent/Assent
 - (c) Subject and Disease Characteristics
 - (d) Efficacy
 - i. Primary Endpoint Assessment
 - ii. Assessment of Secondary Endpoints
 - iii. Assessment of Other Endpoints
 - (e) Safety
 - i. Adverse Events
 - ii. Assessment of Adverse Events
12. Statistical and Analytical Plans
- (a) Sample Size and Power
 - (b) Analysis Sets
 - (c) Statistical Analysis
 - i. General Considerations
 - ii. Descriptive Analysis
 - A. Subjects
 - B. Demographics and Baseline Characteristics
 - C. Prior and Concomitant Medications
 - D. Study Drug Exposure
 - E. Study Drug Compliance
 - (d) Efficacy Analysis
 - i. Analysis of Primary Outcome
 - ii. Analysis of Secondary Outcomes
 - iii. Analysis of Other Outcomes
 - (e) Safety Analysis
 - i. Adverse Events Analysis
 - (f) Interim and IDMC Analyses
 - i. Interim Analysis
 - ii. DSMB Analysis
13. Procedural, Ethical, Regulatory, and Administrative Considerations
- (a) Adverse Event and Serious Adverse Event Documentation, Severity Grading, and Reporting
 - i. Adverse Events

- A. Definition of an Adverse Event
- B. Clinically Significant Assessments
- C. Documentation of Adverse Events
- D. Adverse Event Severity
- E. Adverse Event Causality
- F. Study Drug Action Taken
- G. Adverse Event Outcome
- H. Treatment Given
- ii. Serious Adverse Events
 - A. Definition of a Serious Adverse Event
 - B. Documentation of Serious Adverse Events
 - C. Reporting Serious Adverse Events
 - D. Expedited Reporting and Investigator Safety Letters
- (b) Administrative Requirements
 - i. Ethical Considerations
 - ii. Subject Information and Informed Consent
 - iii. Investigator Compliance
 - iv. Access to Records
 - v. Subject Privacy
 - vi. Record Retention
 - vii. Study Termination
- (c) Data Quality Assurance
- (d) Monitoring
- (e) Electronic Data Capture
- (f) Publications and Clinical Study Report
 - i. Publication of Study Results
 - ii. Clinical Study Report
- 14. References
- 15. Protocol Signature Pages
 - (a) Sponsor Signature Page
 - (b) Investigator Signature Page