Clinical Trial Protocol Assessment Template

1. General Information

Title of Study

Protocol Number

Version

Date

Principal Investigator

Sponsor

2. Background & Rationale

Summary of Rationale

Objectives

3. Study Design

Design Type

Number of Arms/Cohorts

Phase

Randomization/Blinding

4. Study Population

Inclusion Criteria

Exclusion Criteria

Sample Size

5. Study Procedures

Interventions/Treatments

Schedule of Assessments

6. Outcomes & Assessments

Primary Outcome(s)

Secondary Outcome(s)

7. Data Management & Analysis

Data Collection Methods

Statistical Analysis Plan

8. Safety Considerations

Adverse Event Monitoring

Data Monitoring Committee

9. Ethical Considerations

Ethics Approval

Informed Consent Process

10. Other Notes

Additional Comments