Clinical Trial Protocol Submission

1. General Information

Study Title

Principal Investigator

Institution

Protocol Version

Date

---

2. Study Description

Background and Rationale

Objectives

---

3. Study Design

Study Type

Study Phase

Number of Participants

Duration

Randomization & Blinding (if applicable)

---

4. Eligibility Criteria

Inclusion Criteria

Exclusion Criteria

---

5. Intervention & Procedures

Intervention(s)

Study Procedures

---

6. Outcomes

Primary Outcome(s)

Secondary Outcome(s)

7. Statistical Considerations

Statistical Methods

Sample Size Justification

8. Ethical Considerations

Informed Consent

Ethics Committee Approval

Confidentiality