Clinical Trial Ethics Application

1. Project Details

Project Title

Principal Investigator

Affiliation / Institution

Contact Information

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2. Study Summary

Brief Summary

Objectives

Methodology

Study Location(s)

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3. Participants

Participant Population

Inclusion Criteria

Exclusion Criteria

Number of Participants

4. Informed Consent

Process for Obtaining Informed Consent

5. Risks and Benefits

Potential Risks

Risk Management / Mitigation

Potential Benefits

6. Confidentiality

Describe how participant information will be kept confidential

7. Data Management

Data Storage & Security

Data Retention & Destruction

8. Declaration

Declaration by Principal Investigator

Date