

Clinical Trial Research Ethics Compliance Form

Study Information

Study Title

Principal Investigator

Institution

Contact Email

Ethics Committee Name/ID

Date of Submission

Protocol Review

Brief Protocol Summary

Describe any identified ethical issues

Participant Information

Inclusion/Exclusion Criteria

Describe informed consent process

Confidentiality & Data Protection

Measures for data confidentiality and protection

Risk/Benefit Assessment

Assessment of risks and benefits for participants

Additional Compliance

☐ GCP (Good Clinical Practice) adherence

☐ Local regulatory compliance

☐ IRB approval obtained

Declarations

Declaration by Principal Investigator

Signatures

Principal Investigator Signature

Date