

Clinical Trial Ethics Committee Review Form

Study Information

Study Title

Principal Investigator

Institution/Organization

Protocol Number

Date of Submission

Review Type

Review Checklist

- ☐ Compliance with ethical principles (Declaration of Helsinki, GCP, etc.)
- ☐ Adequate and comprehensible informed consent process
- ☐ Acceptable risk/benefit ratio
- ☐ Appropriate protection for vulnerable populations
- ☐ Protection of participant privacy and confidentiality
- ☐ Proper data collection and management plan

Comments by Reviewer

Summary of Ethical Issues

Required Modifications / Conditions

Other Comments

Committee Decision

Decision

Date of Decision

Committee Chairperson/Reviewer

Signature