

Ethics Committee Submission Guide

Healthcare

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This guide explains what the tool produces, how to use the output, and what to watch for. The actual output (draft/report) is generated on the tool page.

Background

Guides an Ethics Committee submission for a clinical study in India — the documents (protocol, ICF, IB, CTRI, insurance, budget, PIS), the process and timelines, and the EC-registration requirement. For an ICF review use the Informed Consent Form Reviewer.

Purpose of this tool & output

Prepare an EC submission

How the output is used

Use the guide to prepare an ethics-committee submission with the protocol, ICF and forms the committee requires.

Who receives it

The Institutional Ethics Committee (IEC/IRB) reviewing the study.

How to submit / file it

Submit to the EC secretariat with the protocol, ICF, CVs and prescribed forms per their timeline.

Who should vet it

The Principal Investigator and a GCP/regulatory expert, before submission.

Important cautions

AI-generated guide; confirm the specific EC requirements and current regulations.

Companion documents

- Clinical Trial Protocol Review
- Informed Consent Form Reviewer
- GCP Compliance Checklist
- CRF Design Helper

This is AI-assisted guidance. Verify with a qualified professional before any binding decision. Fees, authorities and processes vary by state and change over time — confirm with your state authority.