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Clinical Trial Protocol Review

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

Reviews a de-identified clinical trial protocol for structural completeness and ICH E6(R2) GCP compliance — section-by-section gaps, informed-consent checks and India CDSCO notes. A structural review, not scientific validation. For an ICF specifically use the Informed Consent Form Reviewer, and for a synopsis use the Study Protocol Synopsis.

Purpose of this tool & output

Upload a de-identified trial protocol for a structural ICH-GCP compliance review

How the output is used

Use the structural review to check a de-identified trial protocol against ICH-GCP before ethics/regulatory submission.

Who should vet it

A clinical research/GCP expert or the Principal Investigator, to confirm scientific and regulatory soundness.

Important cautions

AI-generated structural review only. Not a scientific or medical validation. A qualified medical monitor, biostatistician, and regulatory expert must review before submission to an ethics committee or regulator.

Companion documents

- Informed Consent Form Reviewer
- GCP Compliance Checklist
- Ethics Committee Submission Guide
- 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.