

FDA Good Clinical Practice 2025 Reference Guide

with ICH GCP Guideline E6(R3)

(April 1, 2025 - March 31, 2026)

- **Code of Federal Regulations (CFR)**
Title 21: Food & Drugs
Revised as of April 1, 2025
 - Part 11: Electronic Records; Electronic Signatures
 - Part 50: Protection of Human Subjects
 - Part 54: Financial Disclosure by Clinical Investigators
 - Part 56: Institutional Review Boards
 - Part 312: Investigational New Drug Application
 - Sections 314.80, 314.81: Post-Marketing Reporting
 - Section 314.126: Adequate and Well-Controlled Studies
- **Index to 21 CFR parts 11, 50, 54, 56, 312, 314**
- **FDA Information Sheet Guidances**
Includes:
 - Frequently Asked Questions on Clinical Research
 - A Guide to Informed Consent
 - Recruiting Study Subjects
 - Frequently Asked Question about FDA Form 1572
 - Pre-Study Screening Tests
 - Foreign Clinical Studies for US Submission
 - FDA Inspections of IRBs and Investigators
- **ICH Guidelines**
 - E6(R3): Good Clinical Practice (ICH Step 4)
 - E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (FDA Step 5)
 - E8(R1): General Considerations for Clinical Trials (FDA Step 5)
- **FDA Guidance Documents**
 - A Risk-Based Approach to Monitoring
 - Questions & Answers on Monitoring
 - Informed Consent (August 2023)
 - Adverse Event Reporting to IRBs
 - Safety Reporting Requirements for INDs and BA/BE Studies
 - FDA Inspections: Compliance Program Guidance #7348.810

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Fda Good Practice Guide

RC Schank



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