

FDA Good Clinical Practice 2024 Reference Guide

(April 1, 2024 - March 31, 2025)

- **Code of Federal Regulations (CFR)**

- Title 21: Food & Drugs**

- Revised as of April 1, 2024

- 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 (Step 5, U.S.)**

- E6(R2): Good Clinical Practice: Integrated Addendum to E6(R1)
 - E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
 - E8(R1): General Considerations for Clinical Trials

- **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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