

## 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

# Fda Good Practice Guide

**David Kirk**



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