Good Clinical Practice Reference Guide

2019
Book 1B

FDA Good Clinical Practice 2018 Reference Guide

(April 1, 2019 - March 31, 2020)

- **Code of Federal Regulations (CFR)**
  Title 21: Food & Drugs
  Revised as of April 1, 2019

  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): Integrated Addendum to E6(R1): Guideline For Good Clinical Practice (Step 5 US + ICH Step 4 Addenda)
  E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
  E8: General Considerations for Clinical Trials

- **FDA Guidance Documents**
  - Adverse Event Reporting to IRBs
  - Safety Reporting Requirements for INDs and BA/BE Studies
  - A Risk-Based Approach to Monitoring
  - FDA Inspections: Compliance Program Guidance #7348.810

- **2019 International Websites on Drug Development**

- **European Directives on GCP**
  - 2001/20/EC and 2005/28/EC

CLINICAL RESEARCH RESOURCES