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

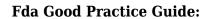
Includes:

- · Frequently Asked Questions on Clinical Research
- A Guide to Informed Consent
- · Recruiting Study Subjects
- Frequently Asked Question about FDA Form 1572
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- 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)
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 - · A Risk-Based Approach to Monitoring
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 - Informed Consent (August 2023)
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Fda Good Practice Guide

F Rizvi



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