Good Clinical Practice Regulations in the US and the EU

2023
Book 1C

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(April 1, 2023 - March 31, 2024)

- **US Code of Federal Regulations (CFR)**
  Title 21: Food & Drugs
  Revised as of April 1, 2023

  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
  Part 314: Applications for FDA Approval to Market a New Drug

- **Index to 21 CFR parts 11, 50, 54, 56, 312, 314**

- **EU Directives on Clinical Trials**
  - 2001/20/EC and 2005/28/EC

- **EU Clinical Trials Regulation No. 536/2014**

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

  E6(R2): Integrated Addendum to E6(R1): Guideline For Good Clinical Practice (Step 5 US)
  E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
  E8(R1): General Considerations for Clinical Trials

CLINICAL RESEARCH RESOURCES