Code of Federal Regulations

FDA Information Sheets

Regulations and Guidance on the Protection of Human Subjects: Clinical Investigator, IRB and Sponsor Responsibilities

(April 1, 2023 - March 31, 2024)

- **FDA Information Sheet Guidances**
  As of April 1, 2023
  - Frequently Asked Questions on Protection of Human Subjects
  - A Guide to Informed Consent
  - IRB Continuing Review of Research
  - Sponsor-Investigator-IRB Interrelationship
  - Subject Recruitment
  - Payments to Study Subjects
  - Subject Screening Tests
  - Treatment Use of Investigational Drugs
- **FDA Guidance on Investigator Responsibilities**
- **FDA Guidance on IRB Responsibilities**
- **OHRP Guidance on Unanticipated Problems and Adverse Events**
- **FDA Bioresearch Monitoring Compliance Program**
  - Monitoring of Clinical Investigators (No. 7348.811)
  - Monitoring of IRBs (No. 7348.809)
- **DHHS Guidance on HIPAA Privacy in Research**
- **U.S. Code of Federal Regulations**
  As of April 1, 2023
  - Title 21, Food & Drugs, Parts 11, 50, 54, 56
  - The Common Rule: Title 45, Part 46
  - 45 CFR 164: Selected Sections on HIPAA and Research

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