Understanding the Clinical Research-related Aspects of the US CFRs (21 CFR Part XX)

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Objectives

• Identify the specific Regulations (CFRs) related to clinical research
• Describe the key aspects of each pertinent Code
• Discuss best practices for compliance and ensuring overall study success
Why is this Topic Important?

• Compliance with the Regulations
• Good Clinical Practice
  – Subject safety
  – Data integrity
  – Product accountability
• Continuing Education
What are the Research-related CFRs?

21 CFR Parts

- 11
- 50
- 54
- 56
- 312
- 314
- 812
- 814
21 CFR Part 11

Electronic Records; Electronic Signatures

- Electronic signatures/records equivalent to paper records and handwritten signatures
- eC RFs/EDC
- EMR
21 CFR Part 50

Protection of Human Subjects
• Protects the rights and safety of research subjects
• Informed consent
• Safeguards for children
21 CFR Part 54

Financial Disclosure by Clinical Investigators

• Disclosure of financial interests to minimize bias
• Reviewed with marketing applications
• Form FDA 3454/3455
21 CFR Part 56

Institutional Review Boards

• Standards for the composition, operation, and responsibility of an IRB
• Full review, expedited review, and exemptions from review
21 CFR Part 312

Investigational New Drug Application

• Procedures and requirements for the use of investigational drugs, including submission of the application
• Exempt from premarket approval requirements
• Sponsor/Investigator responsibilities
• Form FDA 1571
21 CFR Part 314

New Drug Application

• Procedures and requirements for the submission to, and review by, the FDA of marketing applications and abbreviated applications

• Form FDA 356h
21 CFR Part 812

Investigational Device Exemptions

• Procedures for the conduct of device clinical investigations, including requirements for the submission to, and review by, the FDA
• Requirements for labeling
• Sponsor/Investigator/IRB responsibilities
• No FDA template form
21 CFR Part 814

Premarket Approval of Medical Devices

• Procedures for the premarket approval of medical devices, including requirements for the submission to, and review by, the FDA
• Class III devices
• Includes HDEs/ HUDs
• No FDA template form
Best Practices for Study Success

• Know and comply with the Regulations (21 CFR Part XX)

• Follow GCP
  – Disclose financial interests/relationships
  – Submit documents to the IRB for review
  – Adhere to the protocol
  – Complete the CRFs accurately
  – Report AEs/deviations
  – Maintain product accountability

• Have fun!
Questions?

Thank you!