Clinical Pathways

Overview of 21 CFR Part 50 Human Subject Protection and 21 CFR Part 56 IRB/IEC

Course Description

This interactive eLearning provides an overview of 21 CFR Part 50 Human Subject Protection and 21 CFR Part 56 IRB/IEC

Learning Objectives

1. Apply critical thinking techniques for effective implementation of the 21 CFR Part 50 and 56.
2. Learn how these sections of the regulations affect your role in clinical research.
3. Discuss challenges and opportunities in implementing these regulations.

Clinical Pathways

Overview of 21 CFR Part 50 Human Subject Protection and 21 CFR Part 56 IRB/IEC

Course Description

Length: 45 minutes run time plus additional time to complete scenarios and post assessment

This interactive course covers an Overview of 21 CFR Part 50 Human Subject Protection and 21 CFR Part 56 IRB/IEC. Content includes key components of human subject protection, definitions and scope for Part 50, informed consent requirements, elements, & language, the informed consent process, exceptions to informed consent, vulnerable populations, and 21 CFR Part 56, Institutional Review Boards.

Clinical Pathways

Overview of 21 CFR 50 Human Subject Protection and 21 CFR 56 IRB/IEC

1. Protection of Human Subjects
   a. Applicable Regulations
   b. Protection of Human Subjects (21 CFR Part 50)
   c. Informed Consent Guidance from FDA
   d. FDA and OHRP eIC Q&A Guidance
   e. Electronic Informed Consent Guidance
2. Scope and Definitions
   a. Protection of Human Subjects (Subpart A)
   b. Subpart A: 50.1 Scope
   c. Subpart A: 50.3 Definitions
3. IC Requirements and Language
   a. General Requirements of Informed Consent
   b. Coercion vs. Undue Influence
   c. Exculpatory Language & Examples
   d. Examples of Subject Compensation
4. Elements of Informed Consent
   a. Elements of Consent (21 CFR 50.25)
   b. Basic Elements (21 CFR 50.25(a))
   c. ICF Additional Elements (21 CFR 50.25(b))
   d. Review of Amount & Payout Schedule to Research Subjects
   e. www.clinicaltrials.gov (21 CFR Part 50.25(c))
5. Informed Consent Process
   a. The Process
   b. Oral Consent
6. Exceptions to Consent
   a. Exceptions From Obtaining Consent
7. Subpart D
   a. 21 CFR Part 50 - Subpart D
   b. Definitions in Part 50.3
8. Institutional Review Boards
   a. IRBs (21 CFR Part 56)
   b. Purpose & Principles (21 CFR 56 Subpart A)
   c. Basic Criteria for IRB Membership (21 CFR 56.107)
   d. IRB Functions and Operations
   e. IRB/EC Procedures
   f. IRB Document Review and Approval
   g. Expedited IRB Review Procedures (21 CFR 56.100)
   h. Continuing IRB Review After Approval
   i. IRB Records and Reports (21 CFR 56.115)
   j. Types of IRBs
   k. Key Stakeholders Communication Flow
   l. Key Stakeholders Communication Flow for Multi-center Trials
9. 10 Question Post Assessment

Meet the Subject Matter Expert

Sam Sather
MS, BSN, CCRC, CCRA

Sam Sather's current focus of consulting is to promote clinical quality systems for Sponsors/CROs and Investigators/Research Institutions. She has over 35 years of clinical experience, has a Bachelor of Science degree in Nursing and a Master of Science degree in Education with a Specialization in Training and Performance Improvement. Sam has been dual certified by the Association for Clinical Research Professionals (ACRP) for over 15 years as a CCRA and CCRC. She is a current ACRP Fellow, which is awarded to individuals who have made substantial contributions to the Association and the industry at large.

Sam is a frequent speaker at industry conferences and has authored dozens of courses for clinical research training programs in various functional areas. She has multiple training, monitoring, and project management experiences of diverse size and objectives with a variety of global clients.

About Clinical Pathways

Clinical Pathways, LLC is a one-of-a-kind consulting and training firm whose purpose is to deliver affordable, customized, high quality clinical research services in an efficient, amiable, and professional manner. Understanding how to focus on what is essential and truly matters to promote better clinical quality systems for our clients is the key to our approach. Our agile consulting services adapt to the client's unique needs. Whether it is vendor management, SOP development, inspection readiness, RBQM, or an impact and gap analysis, Clinical Pathways has you covered.