HIPAA Training for Clinical Trial Professionals

Course Description

This Health Insurance Portability and Accountability Act (HIPAA) training for Clinical Research Professionals covers best practices for sites and sponsors/CROs working together under HIPAA including use or disclosure of Protected Health Information (PHI) by Covered Entities for research purposes.

Learning Objectives

1. Define key terminology and concepts specific to the HIPAA Privacy Rule in clinical research.
2. Describe when sites are covered entities and the sponsor roles and responsibilities related to the HIPAA Privacy Rule.
3. Discuss the requirements of the Privacy Rule relating to clinical research source documentation use and disclosure.

Inspection Readiness • Audit Preparation • Quality Risk Management Training • CRO & Vendor Oversight Program Development

www.clinicalpathwaysresearch.com

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Length: 60 minutes run time plus additional time to complete scenarios, activities, and post assessment

HIPAA's requirements for the use and disclosure of Protected Health Information (PHI) during the conduct of a clinical trial is not simple and depends on the situation. But there is a way to use a core set of principles and questions that provide an ability to manage and facilitate the needs of all stakeholders. The regulatory authority of HIPAA, the OCR and FDA agree that the two sets of regulations do not conflict and work well together. HIPAA does not restrict the GCP requirements of a site.

Learn the answers to these questions and more in the eLearning course.

1. Did you know that not all clinical trial sites are covered entities?
2. How do you know if a clinical research site is a covered entity?
3. If a site is a covered entity, do you know what they must do to follow HIPAA requirements to safeguard PHI?

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1. Key Terminology & Concepts Specific to HIPAA and Clinical Trials
   a. HIPAA Background
   b. Glossary of Terms
   c. Why was HIPAA Created?
   d. Who Must Follow HIPAA?
   e. Covered Entity
   f. Qualifications of a Covered Entity
   g. Business Associate
   h. Business Associate after HITECH?
   i. Is My Site/Investigator a Covered Health Care Provider?

2. Protected Health Information, Assurances for Covered Entities, Authorization vs. Waiver
   a. Health Information
   b. Health Information Since HITECH
   c. Protected Health Information (PHI)
   d. Individual's Rights Under HIPAA
   e. Maintenance or Transmission of PHI
   f. De-identified PHI
   g. PHI Identifiers
   h. How Can PHI be Used for Clinical Research?
   i. Assurances for Covered Entities
   j. Individual Authorization to Use or Disclosure of PHI
   k. Required Elements of an Authorization for Use or Disclosure of PHI
   l. Waiver of Authorization
   m. Some Questions Regarding Authorizations & Sponsors
   n. Data Use Agreements
   o. Disclosure of PHI for Monitoring
   p. Exception to Review Preparatory to Research (RPR)

3. Security Rule, Privacy Rule, & Enforcement Rule
   a. Distinction Between the Security and Privacy Rule
   b. 21 CFR Part 11 Compliance, HIPAA, and Covered Entity
   c. Security Rule
   d. Enforcement Rule
   e. Privacy Rule: Enforcement Highlights
   f. FDA Q&A from www.fda.gov
   g. PHI Safeguards and Monitoring

4. Sites and Sponsors Working Together Under HIPAA
   a. Good Clinical Practice & Good Privacy Practice
   b. Investigator Oversight & Availability of Records
   c. Remote Clinical Trials
   d. Centralized Monitoring
   e. Some FDA Examples that are Linked to Potential Remote PHI Review
   f. OCR Guidance & FAQ
   g. Sponsor Remote Site Monitoring
   h. Clearly Define Pertinent Source for Remote Review
   i. Remote Clinical Trials
   j. PHI Safeguards and Monitoring
   k. Revision to Processes to Support Remote Review and Access
   l. Support Relationships Between Sites & Sponsors/CROs

5. Extensive Real-life Case Scenarios

6. 10 Question Post Assessment

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Meet the Subject Matter Expert

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 Sather
MS, BSN, CCRC, CCRA

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.