



HIPAA for Clinical Trials

Online Course

£99

Course Overview

This course explains how HIPAA protects participant information while still allowing clinical trials to be conducted effectively and compliantly.

Through structured, easy-to-follow modules, learners gain a solid understanding of the HIPAA Privacy Rule, Security Rule, and Breach Notification Rule, and how these requirements apply throughout the clinical trial lifecycle. The course explores key topics including protected health information (PHI), authorizations and waivers, roles and responsibilities, data handling and security, participant rights, breach management, monitoring and inspections, and the importance of ongoing training and compliance programs.

Learning Objectives

- Explain the purpose of HIPAA and how the Privacy, Security, and Breach Notification Rules apply to clinical research activities.
- Identify what constitutes protected health information (PHI) and apply appropriate safeguards when using, accessing, or sharing it during a clinical trial.
- Recognize the roles, responsibilities, and participant rights defined under HIPAA, including requirements for authorizations, waivers, and disclosures for research.
- Respond appropriately to privacy and security risks, including potential breaches, audits, inspections, and ongoing compliance obligations.

Course Contents:

- Introduction to HIPAA in Clinical Research
- HIPAA Fundamentals
- Protected Health Information (PHI)
- Roles and Responsibilities in Clinical Research
- HIPAA Authorizations in Clinical Trials
- Waivers and Alterations of Authorization
- Use and Disclosure of PHI for Research
- HIPAA and Informed Consent
- Data Handling and Security in Clinical Trials
- HIPAA in Multi-Site and International Trials
- Subject Rights Under HIPAA
- Breaches and Incident Management
- Monitoring, Audits, and Inspections
- Training and Compliance Programs
- Summary and Exam



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Duration:

Approx. 1-2 hours

As with all of our courses, you are able to take this in your own time, on any device and are able to pause and restart from the place you left off. Time taken will vary depending on your experience and how many of the many optional links and activities you choose to view.



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