



# CLINICAL RESEARCH Training Fundamentals

What type of training does your clinical research team need to ensure compliance with the highest regulatory and ethical standards? No matter what type of training your organization requires, be sure it covers these fundamentals.



## U.S. CODE OF FEDERAL REGULATIONS (21 CFR)

- **Part 312** Understand investigational drug regulations, safety reporting requirements, and researcher responsibilities
- **Part 812** Understand federal regulations for investigational medical devices, safety reporting requirements, and researcher responsibilities
- **Parts 50, 56, 54, and 11** Understand and follow guidelines for the protection of human subjects and consent, IRB requirements, financial disclosure, and electronic records and signatures



## GOOD CLINICAL PRACTICE GUIDELINES

- Ensure clinical studies follow all guidelines for ethical conduct, record keeping, and quality assurance



## HUMAN SUBJECTS PROTECTION

- Review ethical principles for human subject research, including informed consent required elements and documentation



## SUBJECT CONFIDENTIALITY – HIPAA AND HITECH

- **HIPAA** Understand how patient privacy laws apply to research and what constitutes a violation
- **HITECH** Understand how the federal expansion of electronic protected health information widens the scope of privacy and security protections and impacts clinical research



## THE HISTORY OF CLINICAL RESEARCH

- Understand how clinical research regulations have evolved and how important events resulted in the protections in place now



## HOW TO ANSWER COMPLIANCE QUESTIONS AND CONCERNS

- Be able to think critically to understand whether an issue is a violation of research requirements and respond with confidence



**IMARC Research** is a contract research organization specializing in training, monitoring, auditing, and consulting services. IMARC now offers affordable online training and continuing education courses designed to prepare professionals and their teams for clinical research compliance. Clinical research fundamentals are covered in IMARC University's Foundation Package, a six-part course that research professionals can take at their own pace. For more information or to explore our courses, visit [imarcresearch.com/university](http://imarcresearch.com/university).