CREATe

Duke Clinical Research Institute

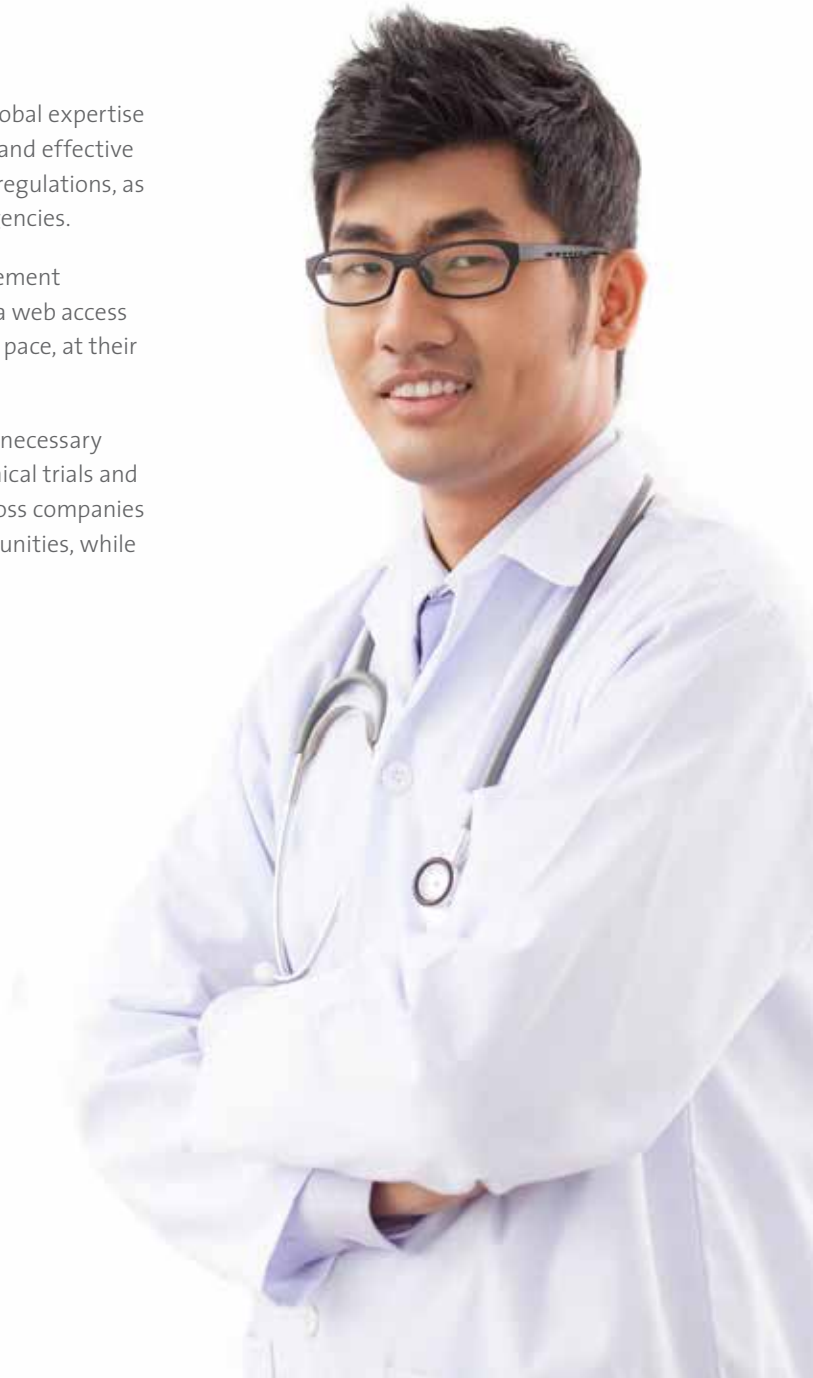
Course Guide

Overview:

Through the CREATe program, clinical researchers can leverage the global expertise of Duke Clinical Research Institute to learn the fundamentals of safe and effective clinical trial conduct and the latest U.S. Food & Drug Administration regulations, as well as ICH guidance and regulations from other global regulatory agencies.

Courses are available through the ComplianceWire® learning management system from UL EduNeering, which delivers educational programs via web access 24 hours a day, seven days a week, so learners can study at their own pace, at their own schedule.

After completing these courses, research site personnel will gain the necessary skills they need to make informed decisions about the conduct of clinical trials and receive a certificate of completion. This certification is applicable across companies and trials, providing valuable credentials that can lead to new opportunities, while eliminating the need for retraining for each new trial.



Course Descriptions:

Evolution of Clinical Research and Drug Safety (DCRI_01)

Clinical research, conducted on human subjects, generates data that can be used to better understand human disease and improve human health.

After you complete this course, you will understand the history of drug development and what circumstances led to regulations. You will also learn why clinical research is important. The course concludes by providing an overview of the key players in clinical research.

Topics include:

- Historical events and laws that shaped research, including the Federal Food and Drugs Act; Food, Drug, and Cosmetic (FD&C) Act; Kefauver-Harris Amendments to the Food and Drugs Act; Nuremberg Code; Declaration of Helsinki; Belmont Report; ICH GCP; and the National Research Act
- Pharmacogenomics
- Benefits of clinical research to society, subjects, investigators, and the healthcare community
- Definitions of key players including regulatory agencies (such as the NIH, EMA, FDA, ICH, and IRB) and those involved in the operations and conduct of clinical research

References:

- FD&C Act
- 45 CFR Part 46
- 21 CFR 56.109
- ICH E4
- ICH GCP 5.18.4
- ICH GCP 1.34, ICH GCP 1.56

Phases of Clinical Research (DCRI_02)

This course provides an overview of the New Drug Application (NDA) process and the various phases of a clinical investigation.

After you complete this course, you will be able to identify the purpose of pre-clinical trials, the Investigational New Drug (IND) Application, and the New Drug Application (NDA). You will be able to identify the phases of clinical research. You will also be able to recognize the classifications of medical devices.

Topics include:

- The role of pharmacodynamics and pharmacokinetics in pre-clinical studies
- The Investigational New Drug (IND) Application
- The New Drug Application (NDA)
- Phases I, II, III, IIIb, and IV
- The three regulatory classifications of medical devices
- Investigational Device Exemption (IDE)

References:

- 21 CFR Part 312
- 21 CFR 50.24
- 21 CFR Part 812
- Form FDA 1572 (Statement of Investigator)
- Pre-Market Notification, also called PMN or 510(k)
- Pre-Market Approval (PMA)

How is Clinical Research Regulated? (DCRI_03)

This course provides you with an overview of the clinical research regulatory environment and Good Clinical Practice (GCP) guidelines.

After you complete this course, you will be able to identify which regulatory agency establishes regulations for a specific type of clinical research study. You will also be able to recognize when and how regulations and requirements apply to specific clinical research studies.

A sample from the "How is Clinical Research Regulated?" course.

Topics Include:

- The definition, evolution, and goal of GCP
- U.S. regulatory agencies
- ICH Guidelines
- Guidance documents
- Review boards
- SOPs

References:

- ICH GCP, ICH 1.55
- 45 CFR Part 46
- 21 CFR Parts 11, 50, 54, 56, 312, 803, 812
- Food, Drug, and Cosmetic (FD&C) Act
- Food and Drug Administration Modernization Act (FDAMA)
- Food and Drug Administration Amendments Act (FDAAA)

Audits and Inspections: Identifying Fraud and Misconduct (DCRI_04)

Proper conduct of clinical research studies requires compliance with certain rules and regulations. Audits and inspections of clinical research studies are conducted to ensure compliance with regulations.

This course examines the guidelines for preparing for audits and inspections, which ensure compliance. It also explains the seriousness of research misconduct and provides examples of research misconduct.

Topics include:

- Who conducts audits and inspections
- Preparing for audits and inspections
- Potential FDA inspection outcomes
- Types of misconduct including fabrication, falsification, and plagiarism
- Determining misconduct through allegations, inquiries, and investigations

References:

- 21 CFR Parts 50, 56, 312, and 812
- Form FDA 483 (Notice of Inspectional Observations)
- Warning Letter

Responsibilities of a Clinical Research Coordinator (CRC) in FDA-Regulated Studies (DCRI_05)

This course explores the roles and responsibilities of a clinical research coordinator (CRC) within an FDA-regulated clinical study and explains what the regulations require of the CRC.

After completing this course, you will be able to recognize the roles and responsibilities of a CRC in clinical studies. You will also be able to identify the qualities that are required to make a CRC successful.

Topics include:

- The definition, roles, and responsibilities of a CRC
- Skills and abilities necessary for success
- Principal investigator responsibilities and what can be delegated

References:

- Form FDA 1572 (Statement of Investigator)

Responsibilities of Investigators Conducting FDA-Regulated Studies (DCRI_06)

This course explains the roles and responsibilities of the investigator conducting FDA-regulated clinical studies and explores what the regulations require of the investigator.

After you complete this course, you will be able to recognize the role of the investigator and subinvestigator in clinical studies. You will be able to identify what the regulations require of the investigator and subinvestigator and the responsibilities that the investigator and subinvestigator accept when beginning a study.

Topics include:

- The definition, roles, and responsibilities of an investigator
- Form FDA 1572 (Statement of Investigator)
- FDA requirements for the investigator
- Roles of the subinvestigator, sponsor, and sponsor-investigator
- Investigator disqualification

References:

- Form FDA 1572 (Statement of Investigator)
- Form FDA 483
- FD&C Act
- CFR Part 505(i)
- 21 CFR 812.43(c)
- 21 CFR Part 50
- 21 CFR 312.30, 21 CFR 312.61, 21 CFR 312.64, 21 CFR 312.66, 21 CFR 312.70
- 21 CFR 56.102

Human Research Protection Program (DCRI_07)

Human research protection programs (HRPPs) have received heightened attention in the last several years. Any individual, group, entity, department or committee that has an obligation related to a research enterprise is considered to be part of an HRPP.

After taking this course, you will understand the purpose of an HRPP. You will also learn about the development of human subject protection and the components of an HRPP.

Topics Include:

- The scope of an HRPP
- Evolution of human subject protection
- Historical events affecting human subject protection
- The Association for the Accreditation of Human Research Protection Programs (AAHRPP)

References:

- 45 CFR 46 Subpart A (The Common Rule)
- The Belmont Report

Informed Consent Part I (DCRI_08)

This course introduces informed consent regulations and guidelines, the informed consent process, and the roles and responsibilities of clinical research professionals in ensuring the protection of human subjects through the informed consent process.

After completing this course, you will be able to identify key historical events that led to current informed consent regulations and guidelines. You will also recognize today's informed consent process and the documentation requirements that are involved in the process.

Topics include:

- Ethical doctrines
- Required informed consent elements (FDA and ICH GCP)
- Long-form and short-form consent
- Managing the consent process
- Consent form revisions and re-consenting

A sample from the Informed Consent Part I course.

References:

- 21 CFR Part 50
- 21 CFR 312.62(b)
- 45 CFR 46.116
- Tuskegee Syphilis Study
- Nuremberg Code
- Kefauver-Harris Amendments
- World Medical Association Declaration of Helsinki
- Belmont Report
- 45 CFR 46 Subpart A (The Common Rule)
- ICH Guidelines

Informed Consent Part II (DCRI_09)

This course introduces informed consent regulations and guidelines for special circumstances and populations to ensure the protection of human subjects through the informed consent process. You will be able to recognize special circumstances that require the informed consent process to go beyond the typical requirements and to identify how to meet the additional needs of special populations in order to appropriately obtain informed consent.

Topics include:

- Identifying situations where informed consent prior to study participation is not required
- Emergency research
- Minimal-risk studies
- Definition of vulnerable subjects
- Pediatric assent and parent/guardian permission
- Designing reader-friendly informed consent forms
- Translating informed consent documents

References:

- 21 CFR 56.102(i)
- ICH GCP 1.61
- 45 CFR Part 46
- 21 CFR Part 50, Subpart D
- 21 CFR 50.25, 21 CFR 50.27
- ICH E6

Drug Safety and Adverse Event Reporting (DCRI_10)

Consumers look to regulatory authorities for protection from harmful pharmaceutical products. In turn, regulators depend on their regulatory system and the pharmaceutical industry's compliance with established regulations to prevent unsafe products from reaching the public.

This course introduces you to adverse event reporting and post-marketing surveillance. The course also explores the necessity of drug safety and pharmacovigilance.

Topics include:

- Definitions for adverse event and pharmacovigilance
- The importance of monitoring adverse events
- The stages of pharmacovigilance
- The different types of safety-related events that can occur during a clinical study
- Sponsor's responsibilities regarding notifying FDA of events
- The role of monitoring in protecting human subjects
- Common errors when documenting safety events

References:

- ICH GCP
- ICH E2B
- 21 CFR 312.32, 21 CFR 312.50, 21 CFR 312.64(b)
- 21 CFR 314.80
- ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice E6(R1), 1
- Medical Dictionary for Regulatory Activities (MedDRA)

Recruitment, Retention, and Lost to Follow-Up (DCRI_11)

This course explores the study recruitment process and discusses how to retain subjects and perform follow-up.

After completing this course, you will be able to recognize how to build a recruitment and enrollment plan and how to facilitate subject retention. You will be able to recognize how to manage subject withdrawal and subjects who are lost to follow-up.

Topics include:

- How to develop a recruitment plan
- How to identify potential subjects
- Acceptable ways to advertise for subjects
- The purpose of a screening log
- Potential barriers to recruitment
- Elements of an enrollment packet
- How to best manage competing studies at the same site
- The role of informed consent
- The importance of reviewing the enrollment process
- Ensuring subject retention
- Protocol compliance
- Managing subject withdrawal

References:

- Margaret B. Liu and Kate Davis. A Clinical Trials Manual from the Duke Clinical Research Institute: Lessons From a Horse Named Jim. 2nd ed. West Sussex, UK. Blackwell-Wiley; 2010
- The Belmont Report

CREATe Refresher Course (DCRI_12)

This course is delivered to participants after the Core Knowledge curriculum is completed. The course takes about 20 minutes to complete.

This refresher course reviews the content in those courses, including guidelines for protecting human subjects, ICH, phases of an investigation, what the CRC is and the skills, responsibilities and expectations of the CRC.

This course also covers the study subject recruitment process, translation of informed consent documents and subject withdrawal, and preparing for audits/inspections.

After completing this course, learners will be able to recall key content from previous courses that will help to reinforce critical aspects of the clinical trial process.

Data Collection (DCRI_13)

This course identifies what electronic data capture (EDC) is and how EDC systems work. You will be able to recognize data sources and types of queries, as well as how to enter data.

You will also be able to identify how databases in an EDC system are locked and how the information is then delivered to the study team.

Topics include:

- Security
- Privacy
- Data sources
- Queries
- Database lock

References:

- 21 CFR Part 11
- Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule
- The International Council on Harmonisation (ICH) Guidelines (E6)
- 21 CFR 11.10

China Food and Drug Administration (CFDA): Clinical Trial Regulation in China (DCRI_14)

This course provides an overview of clinical trial regulation in China, as overseen by the China Food and Drug Administration of the People's Republic of China (CFDA). After completing the course, you will be able to identify the high-level requirements of CFDA regarding clinical trials and recognize how a clinical trial is able to operate according to CFDA policies.

Topics include:

- Drug Administration Law of the People's Republic of China
- Regulations for Implementation of the Drug Administration Law of the People's Republic of China
- Clinical Trial Permit application

References:

- Article 29 of the Drug Administration Law
- CFDA Order 28

The Organizations Behind CREATe:

Duke Clinical Research Institute
From Thought Leadership to Clinical Practice

The Duke Clinical Research Institute (DCRI, www.dcri.org), the world's largest academic research organization, is known for conducting groundbreaking multinational clinical trials, managing major national patient registries, and performing landmark outcomes research.

The DCRI conducts ongoing research in 20 therapeutic areas with research collaborations in more than 60 countries, coordinated by more than 200 Duke University faculty and 1,100 staff.

The DCRI is the coordinating center for multiple NIH-supported investigator networks. Through its clinical research projects, the DCRI has enrolled more than one million participants in clinical studies.

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.

Learn how your company can elevate the quality of global clinical research.

To get started, contact Pat Thunell at UL (609-627-5302) to arrange a call with representatives from the Duke Clinical Research Institute and UL.