Good Clinical Practice

Have you recently learned that you need additional training to be compliant? Are you unsure of where to start? UCLA offers two GCP courses through the CITI Program. CE/CME credits for Physicians, Nurses, Psychologists, and other disciplines are available for both courses and it is very simple to get started.

The CITI Good Clinical Practice (GCP) Basic Course is an overview of GCP. Some units on campus require this course, but it is optional for the HRPP. Be sure to check with your departmental GCP training requirements.

The CITI Good Clinical Practice (GCP) Optional Modules Course is a 13-module program that discusses good clinical practice as it relates to clinical trials of both drugs/biologics as well as devices. The GCP modules are described below and are intended for use by research personnel involved in conducting drug, device, or biologic studies and should be taken in the order they are listed. The optional course takes approximately 4 hours to complete.

GCP Introduction

This module provides a listing of all modules in the course, required computer system parameters, and mechanisms for obtaining CE credits.

Overview of New Drug Development

This module describes the role of industry sponsors in the conduct of clinical trials under an Investigational New Drug (IND) application in the U.S. according to FDA regulations. It provides an overview of important definitions, procedures and timelines involved in the development of a new drug.

International Conference on Harmonisation (ICH): GCP Requirements

The purpose of this module is to provide a basic understanding of the role of the International Conference on Harmonisation (ICH) Guidelines and the impact on conducting human clinical research according to Good Clinical Practice (GCP). The purpose of ICH and the basic requirements for compliance with ICH are described. How ICH fits with U.S. federal regulations regarding clinical research is discussed.

Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices

This module discusses topics important to researchers who are also the sponsor of a study. These individuals are conducting investigator-initiated studies. Topics discussed include how to determine whether an Investigational New Drug (IND) application or an Investigational Device Exemption (IDE) is required, the role of the sponsor-investigator, documentation required for INDs and IDEs, and reports that must be submitted to the FDA for active INDs/IDEs.

Investigator Obligations in FDA-Regulated Clinical Research

Investigators assume responsibilities when participating in clinical investigations sponsored by pharmaceutical companies under IND requirements. This module describes the commitments and obligations assumed by investigators, including those contained in Form FDA 1572, Statement of Investigator. A discussion of the investigator's relationship with the sponsor organization as well as the investigator's commitments to the subjects, the Institutional Review Board/Ethics Committee (IRB/IEC), and the U.S. Food and Drug Administration (FDA) is included.

Managing Investigational Agents According to GCP Requirements

This module focuses on specific requirements for the management of investigational products by principal investigators. This includes requirements for storage of investigational agents as well as recording the receipt, use, and final disposition of investigational agents. The module also reviews the management requirements for the use of investigational agents by study subjects.

Conducting Clinical Trials of Medical Devices

This module reviews the responsibilities of investigators conducting clinical research involving medical devices. It includes a discussion of the difference between devices involving significant risk versus nonsignificant risk. The characteristics and marketing requirements for Class I, II, and III devices are reviewed

Informed Consent

This module discusses the informed consent guidelines, the required and optional elements of informed consent and the process for obtaining informed consent. There is also a discussion of the differences between FDA and DHHS regulations.

Detection and Evaluation of Adverse Events

This module describes the obligation of industry research sponsors to monitor the progress of clinical trials under an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application in the U.S. The types of site visits conducted by industry sponsors are described along with the basic requirements for each type of site visit. The module describes the role of the investigative site during interactions with industry sponsors as well as the requirements for site record-keeping in studies regulated by the U.S. Food and Drug Administration (FDA).

Reporting Serious Adverse Events

This module discusses the criteria for reporting SAEs to regulatory agencies, sponsors, etc. The discussion includes definitions for "serious" and "unexpected" adverse events and reviews the requirements for reporting of SAEs within time frames required by FDA and ICH. The module provides categories of relatedness to the investigational agent for SAEs and how they affect reporting.

Monitoring of Clinical Trials by Industry Sponsors

This module provides a basic understanding of monitoring, audits, and inspections of clinical trials conducted according to standards for good clinical practice (GCP). It describes the different entities that can inspect or audit a clinical trial and investigator and the factors that can determine whether an investigator will be audited. The purpose of the FDA

Bioresearch Monitoring Program is discussed.

Audits and Inspections in Clinical Trials

This module provides a basic understanding of monitoring, audits, and inspections of clinical trials conducted according to standards for good clinical practice (GCP). It describes the different entities that can inspect or audit a clinical trial and investigator and the factors that can determine whether an investigator will be audited. The purpose of the FDA Bioresearch Monitoring Program is discussed.

Training Resources and Questions?

- FDA Regulations Relating to Good Clinical Practice and Clinical Trials
- Article on GCP training in pediatric oncology
- Visit the CITI Registration FAQs if you have questions about the CITI program. For GCP related questions, contact us at ResearchGo.

Partner Site Contacts - Training

- LA BioMed
- Cedars-Sinai

LA BioMed:

EHR Trainings (ORCHID and i2b2 training offered by Liz Chen, Liz Chen, MBA, (310) 781-3601, lchen@labiomed.org)

Clinical Research Coordinators (SOCRA Chapter continuing education lectures; Clinical Research Coordinator Council) CTSINavigation@labiomed.org

Good Clinical Practice (CITI) Ernestina Yiadom, 310-222-3624, eyiadom@labiomed.org

Cedars-Sinai

- Clinical Research Professional Orientation for new hires and existing research staff. To learn more these courses, or to enroll, contact Maggie Benton, grant and contract coordinator, 323-866-6921, maggie.benton@cshs.org.

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