

CTR 110
INTRODUCTION TO CLINICAL RESEARCH

COURSE DESCRIPTION:

Prerequisites: Enrollment in the Clinical Trials Research Associate program or permission of program director

Corequisites: None

This course provides a comprehensive introduction to the clinical research process and its history and evolution. Topics include phase of clinical trials, protection of human subjects, roles of the clinical research teams, and responsibilities of clinical research organizations. Upon completion, students should be able to prepare an organizational chart depicting a typical research team, defining the roles or responsibilities of each member. The student should also be able to describe the product approval process and discuss the general conduct of a typical clinical trial. Course Hours Per Week: Class, 3. Semester Hours Credit, 3.

COURSE OBJECTIVES:

Upon completion of this course, the student will demonstrate basic cognitive and practical knowledge and skills in each of the following areas:

- a. Evolution and history of the clinical research process.
- b. Evolution and history of the protection of human subjects in clinical research.
- c. Overall process of clinical research development of drugs, devices and biologics.
- d. Classification of clinical trial designs in phases 0 through IV.
- e. Define the roles and responsibilities of clinical research positions as they relate to the clinical research process.
- f. Define the roles of various organizations that may be involved in the clinical research process.
- g. Identify the members of a clinical research study team, their roles and interdependencies.
- h. Identify the overall conduct of a typical clinical trial.
- i. Identify necessary skills and attributes of the clinical research professional.
- j. Exhibit professional demeanor and utilize effective communication skills.
- k. Identify professional research associations and their respective roles.

OUTLINE OF INSTRUCTION:

- I. Course outline and objectives
- II. Evolution and history of the clinical research process
 - A. U.S. laws governing the development and marketing of drugs and devices
 - B. Bioresearch Monitoring Program
 - C. Federal regulations and ICH guidelines

- III. Evolution and history of the protection of human subjects in clinical research.
 - A. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research
 - B. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
 - C. Nuremberg Code and the Declaration of Helsinki
 - D. Belmont Report

- IV. Overall process of clinical research development of drugs, devices and biologics
 - A. Government agencies and international initiatives involved in clinical research
 - B. New drug and biologic development and marketing approval process
 - C. Medical device development and marketing approval process

- V. Classifications of clinical trial designs in phases I through IV

- VI. Define the roles and responsibilities of the clinical research positions as they relate to the clinical research process
 - A. Study coordinator
 - B. Clinical pharmacist
 - C. Statistician
 - D. Project leader/manager
 - E. Auditor
 - F. Clinical investigator
 - G. Clinical research associate/monitor
 - H. Data manager
 - I. Medical officer
 - J. Medical writer
 - K. Regulatory affairs personnel

- VII. Define the roles of organizations which may be involved in the clinical research process
 - A. Pharmaceutical, biotech and medical device companies
 - B. Clinical research organizations
 - C. Site management organizations
 - D. Institutional review boards
 - E. Investigative sites
 - F. Academic research organizations
 - G. Research laboratories
 - H. Research funding agencies (e.g., private foundations, governmental agencies and non-governmental agencies)
 - I. U.S. Food and Drug Administration and other regulatory agencies

- VIII. Identify the members of a clinical research study team, their roles and interdependencies

- IX. Identify the overall conduct of a typical clinical trial
 - A. Selecting and initiating investigators
 - B. Study conduct on behalf of the sponsor including investigator product shipment, monitoring, adverse event reporting and data management
 - C. Study conduct on behalf of the site including HE reporting
 - D. Study termination

- X. Identify necessary skills and attributes of the clinical research professional
 - A. Professional demeanor
 - B. Knowledge and experience
 - C. Communication skills
 - D. Attention to detail
 - E. Affiliation

- XI. Identify professional research associations and their respective roles
 - A. Society of Clinical Research Associates (SoCRA)
 - B. Association of Clinical Research Professionals (ACRP)
 - C. Drug Information Association (DIA)
 - D. Regulatory Affairs Professional Society (RAPS)
 - E. Society of Clinical Data Management (SCDM)

REQUIRED TEXTBOOKS AND MATERIALS:

Liu, M., and Davis, K. Lessons From a Horse Named Jim. Durham: Duke Clinical Research Institute (2001).

STATEMENT FOR STUDENTS WITH DISABILITIES:

Students who require academic accommodations due to any physical, psychological, or learning disability are encouraged to request assistance from a disability services counselor within the first two weeks of class. Likewise, students who potentially require emergency medical attention due to any chronic health condition are encouraged to disclose this information to a disability services counselor within the first two weeks of class. Counselors can be contacted by calling 686-3652 or by visiting the Student Development Office in the Phail Wynn Jr. Student Services Center, room 1309.