CTR 110 Introduction to Clinical Research

COURSE DESCRIPTION:

Prerequisites: Enrollment in the Clinical Trials Research Associate (CTRA) program or permission of the CTRA 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.

LEARNING OUTCOMES:

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

1. Upon completing requirements for this course, the student will be able to:
2. Evolution and history of the clinical research process.
3. Evolution and history of the protection of human subjects in clinical research.
4. Overall process of clinical research development of drugs, devices and biologics.
5. Classification of clinical trial designs in phases 0 through IV.
6. Define the roles and responsibilities of clinical research positions as they relate to the clinical research process.
7. Define the roles of various organizations that may be involved in the clinical research process.
8. Identify the members of a clinical research study team, their roles and interdependencies.
9. Identify the overall conduct of a typical clinical trial.
10. Identify necessary skills and attributes of the clinical research professional.
11. Exhibit professional demeanor and utilize effective communication skills.
12. Identify professional research associations and their respective roles.

OUTLINE OF INSTRUCTION:

I. Course objectives and overview of clinical research
   A. Define the scope of clinical research
   B. Review of interventions that undergo a clinical research process

II. Evolution and history of clinical research processes and the ethics of human subjects research
   A. Review U.S. laws governing the development and marketing of drugs and devices
   B. Describe Food and Drug Administration Oversight of drug development
   C. Review International Council on Harmonization (ICH) guidelines
   D. Discuss the importance of Good Clinical Practice

E. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
F. Review the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report

III. Clinical research development of drugs, devices and biologics
A. List Government agencies and international initiatives involved in clinical research
B. Explain the new drug and biologic development and marketing approval process
C. Outline the medical device development and marketing approval process
D. Describe classifications of clinical trial designs in phases I through IV

IV. Roles and responsibilities of key players in the clinical research process
A. Sponsors: Pharmaceutical, biotech, and medical device companies; governmental agencies, private foundations
B. Contract Research Organizations: Clinical Research Associate, Clinical Trials Associate
C. Investigative sites and Site Management Organizations: Principal Investigator, Co-Investigator, Sub-Investigator, Clinical Research Coordinator, Research Assistant, Recruitment Specialist
D. Academic Medical Centers and Academic Research Organizations
E. Data Management Professionals: Data Specialist, Data Manager, Data Analyst
F. Institutional Review Boards, Regulatory Affairs Quality, and Compliance
G. Clinical Laboratories
H. Data and Safety Monitoring Boards
I. Third Party Vendors: software companies, research technology vendors

V. Conduct of a typical clinical trial
A. Review activities associated with Study Start-Up
i. Identifying a research question, study objectives, and target population
ii. Overview of key documents: the Investigator's Brochure, study protocol
iii. Key features of trials: blinding, randomization, placebo
iv. Site selection process
v. Investigational Product management
vi. IRB approval process
vii. Site readiness and activation
B. Review activities associated with Study Conduct
i. Recruitment of subjects
ii. Obtaining informed consent
iii. Determining subject eligibility
iv. Conducting study assessments
v. Clinical monitoring
C. Review activities associated with Study Close-Out
i. Product disposition
ii. Site close-out
iii. Data lock and analysis
iv. Reporting study results

VI. Participant safety in clinical trials
    A. Define safety events: adverse events, adverse drug reactions, unanticipated problems
    B. Categorize safety events: seriousness, severity, relatedness, expectedness
    C. Describe investigator responsibilities for reporting safety events
    D. Describe sponsor responsibilities for reporting safety events

VII. Clinical Data
    A. Review the overall flow of data in a clinical trial
    B. Describe Electronic Data Capture (EDC) and data collection
    C. Introduce Case Report Forms (CRFs)
    D. Define Quality Assurance and data monitoring
    E. Describe database lock and archival

VIII. Patient-Centered Clinical Research
    A. Compare product-centered versus patient-centered approaches to research
    B. List motivators and barriers to clinical research participation
    C. Explain the importance of diversity in clinical research and equitable access to clinical trials

IX. Professional Development as a Clinical Research Professional
    A. Review career pathways in clinical research
    B. Describe required technical skills and soft skills
    C. List professional clinical research organizations: SOCRA, ACRP, DIA, RAPS, SCDM

REQUIRED TEXTBOOK AND MATERIAL:

The textbook and other instructional material will be determined by the instructor.