CTR 130 Clinical Research Management

COURSE DESCRIPTION:

Prerequisites: CTR 115
Corequisites: None

This course introduces the student to the elements involved in implementing, monitoring and managing a clinical study from the perspective of the Sponsor or contract research organization. Topics include overall project planning, development of study goals, preparation of budget and contracts, implementation of monitoring visits, and effective management of research sites. Upon completion, students should be able to design and prepare a plan for the implementation and management of a sample clinical research project. Course Hours Per Week: Class, 4. Semester Hours Credit, 4.

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. Develop an overall plan for a specified clinical research project
2. Conduct study startup activities for and coordinate identified research projects
3. Describe the process involved in the development of a research study budget
4. Plan, prepare, and conduct evaluation, initiation, periodic monitoring, and termination visits
5. Effectively manage research sites and handle study challenges
6. Collect and evaluate research data for completeness, compliance, and accuracy
7. Discuss the preparation for and conduct of a sponsor quality assurance audit
8. Identify and exhibit professional and behavioral skills required of the Clinical Research Associate

OUTLINE OF INSTRUCTION:

I. Develop an overall plan for a specified clinical research project
   A. Outline the steps of drug development from the identification of a new chemical entity or device through marketing approval
   B. Identify the critical elements of a monitoring plan and devise a monitoring plan for a typical study

II. Conduct study startup activities for and coordinate identified research projects
   A. Develop an overall plan for a specified clinical research trial
   B. Identify the problems that can commonly occur between clinical research organizations and clients
   C. Describe the lines of communication needed between project team members and clinical trial management
   D. Describe the use, design, and importance of set timelines in a well-coordinated research project
   E. Discuss delegation of responsibilities and outsourcing to a contract research organization (CRO) and considerations for this relationship
   F. Describe the components of a typical bid, proposal and contract with CROs

G. Participate in study start up activities including site identification and selection, essential document collection and organization in a Trial Master File, monitoring project data in a Clinical Trial Management System, and investigational product shipment

III. Describe the process involved in the development of a research study budget
   A. List the considerations in estimating study costs and a site budget
   B. List and analyze the budget components for a specified clinical trial relative to cost effectiveness
   C. List and identify the types of clinical research organizations

IV. Plan, prepare, and conduct evaluation, initiation, periodic monitoring, and termination visits
   A. Discuss the regulatory requirements currently in place for the protection of research subjects, including informed consent and FDA requirements
   B. Describe these visits and develop an agenda for each type
   C. Describe the responsibilities of the monitor and the site personnel for each type of visit
   D. Identify the components needed in a summary report for each type of visit
   E. Develop a site feasibility questionnaire
   F. Review data for each subject visit
   G. List the roles and responsibilities of the site and the monitor relative to subject data documentation and verification
   H. List the most common errors made in source documentation
   I. List the most common errors made in case report forms
   J. Differentiate between an adverse event and a serious adverse experience
   K. Describe the process for reporting adverse events and serious adverse experiences
   L. Discuss the regulatory criteria utilized in the conduct of a research study
   M. Identify the challenges of a monitor while traveling on site visits
   N. Develop a monitoring report providing feedback to the investigator and site coordinator

V. Effectively manage research sites and handle study challenges
   A. Outline the basic procedures and tasks needed to implement a clinical study
   B. List the qualifications for the investigator, study coordinator, and monitor in conducting research in Phase I, Phase II, and Phase III clinical trials
   C. Develop sample procedures for the management of a research site, including recruiting, budgeting, and timelines
   D. Define the responsibilities and roles of key personnel participating in the management of a research site
   E. Describe the regulatory documents required of a research site
   F. Describe the databases, logs, and files utilized in the maintenance of a study site
   G. List the ways in which site monitors determine the quality of a site performance
   H. List the areas that the monitor will check to assure the quality performance of a research site
   I. Differentiate between the roles of a monitor and the site in the preparation, maintenance, and submission of required reports

VI. Collect and evaluate research data for completeness, compliance, and accuracy

A. Perform source document verification on typical study cases
B. Review data collection forms for completeness and accuracy
C. Review essential documents collected during a clinical trial
D. Review research data for subject safety

VII. Discuss the preparation for and conduct of a sponsor quality assurance audit
A. Describe the difference between a monitoring visit and a sponsor audit
B. Discuss preparation for a QA audit
C. Describe the purpose of a QA audit and typical findings
D. Review the outcomes of audits
E. Identify instances of scientific misconduct

VIII. Identify and exhibit professional and behavioral skills required of the Clinical Research Associate
A. Describe technical skills required for Clinical Research Associates
B. Describe soft skills required for Clinical Research Associates
C. Discuss professional development for Clinical Research Associates

REQUIRED TEXTBOOK AND MATERIAL:

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