CTR 225 Data Collection

COURSE DESCRIPTION:

Prerequisites: CTR 215
Corequisites: None

This course is designed to instruct the student on the data collection, validation and quality assurance processes of a clinical research study as conducted by the data management staff. Topics include the development and implementation of data review and data collection, the development of the validation program and the function, conduct and follow-up of a quality assurance audit of data. Upon completion, students should be able to develop and implement a plan for data collection, validation and quality assurance for a clinical research study. Course Hours Per Week: Class, 1, Lab, 2. Semester Hours Credit: 2.

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 and implement strategies for data collection and capture
2. Understand the validation program
3. Assist in the review, resolution and tracking of data errors
4. Develop a Quality Assurance Plan for a clinical research study

OUTLINE OF INSTRUCTION:

I. Develop and implement data collection strategies.
   A. Sub-list item escribe best practices and resources required for standardizing data collection, capture, management, analysis and reporting
   B. Identify new technologies and techniques which enhance the quality, conduct and safety of the clinical study
   C. Describe commonly collected safety and efficacy data
   D. Develop data collection strategy to align with mock protocol
   E. Apply principles of patient and site focused design to minimize data collection burden on patient and site staff

II. Understand the validation program
   A. Analyze mock protocol to identify study objectives, endpoints and Critical to Quality (CTQ) factors
   B. Describe methods for performing data and systems validation
   C. Relate the concept of "fit for purpose" to data validation
   D. Develop data validation specifications to align with mock protocol
   E. Apply principles of patient and site focused design to minimize data validation burden on patient and site staff
   F. Relate essential document requirements to data and systems validation

III. Assist in the review, resolution and tracking of data errors

A. Summarize query management purpose and process
B. Relate Quality by Design (QBD) and Quality Risk Management (QRM) to query and discrepancy management
C. Develop standard query text to align with mock validation specifications
D. Perform query management tasks within EDC application

IV. Develop a Quality Assurance Plan for a clinical research study
    A. Analyze mock protocol to identify study objectives, endpoints and Critical to Quality (CTQ) factors
    B. Create critical data review strategy to align with mock protocol
    C. Describe the steps taken to prepare for an audit or inspection
    D. Summarize the purpose and process for managing Corrective and Preventive Action Plans (CAPA)

REQUIRED TEXTBOOK AND MATERIAL:

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