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.

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

OUTLINE OF INSTRUCTION:

A.  Develop and implement data collection strategies.

1.  Create data collection guidelines
2.  Develop and implement guidelines for data review
3.  Review data for accuracy and clarity
4.  Discuss methods for data capture including data entry, fax based data capture and electronic data capture (remote data entry)

B.  Understand the validation program.

1.  Describe the data validation process.
2.  Develop edit specifications.
3.  Describe self-evident changes.
4.  Conduct a review of validation output.
C. Assist in the review, resolution and tracking of data errors
   1. Describe the process for query handling
   2. Generate and resolve manual and electronic queries
   3. Discuss query tracking and database update
   4. Describe components of an audit trail

D. Develop a Quality Assurance Plan for a clinical research study
   1. Describe quality control and quality assurance activities.
   2. Describe types of quality assurance audits, data points audited and required error rates.
   3. Define timelines for audits.
   4. Develop an audit report.

REQUIRED TEXTBOOKS AND MATERIALS:

To be announced by Instructor.