CTR 215
DATA MANAGEMENT CONCEPTS

This course is designed to discuss the elements involved in implementing and managing a clinical study from the perspective of the Data Manager. Topics include development of the data management plan, coordination of data collection and capture, plan the closure and archival of study materials and participate in project management activities. Upon completion, students should be able to design, prepare and execute a complete data management plan for the implementation and management of a sample clinical research project. Course Hours Per Week: Class: 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:

1. Develop and coordinate a data management plan for a clinical research project.
2. Understand and coordinate the relationship between the contract research organization and Sponsor.
3. Understand appropriate communication between the CRO, Sponsor and clinical research site.
4. Assist in the planning and implementation of a clinical research project.
5. Understand procedures for database lock and data archival.

OUTLINE OF INSTRUCTION:

A. Develop and coordinate a data management plan for a clinical research project.
   1. Describe the key elements of a data management plan.
   2. Describe the typical flow of data in a clinical trial.
   3. Develop a data management plan.
   4. Describe project scope and timelines.

B. Understand and coordinate the relationship between the contract research organization and Sponsor.
   1. Discuss the role of the data manager.
   2. Describe the relationship between the Sponsor and outsource providers.
   3. Describe the process of selecting a data management vendor.
   4. Defines deliverables and milestones for a data management project.

C. Understand appropriate communication between the CRO, Sponsor and clinical research site.
   1. Establish a communication plan between study personnel.
   2. Understand data management standard operating procedures.
   3. Identify the roles and responsibilities of the Sponsor versus contract research organization.

D. Assist in the planning, implementation and conduct of a clinical research project.
   1. Establish study timelines.
   2. Describe study startup activities.
   3. Describe management activities of the project.

E. Understand procedures for database lock and data archival.
   1. Describe the process for the database lock.
   2. Describe the process for the need and process for database unlock.
   3. Develop a process for data archival.

REQUIRED TEXTBOOKS AND MATERIALS:

To be announced by Instructor.