

CTR 210
RESEARCH DATA AND REPORTS

COURSE DESCRIPTION:

Prerequisites: CTR 120

Corequisites: None

This course introduces the student to the organization and management of study data and the effective presentation of data in reports. Topics include database structures, data management systems, quality assurance, data confidentiality and security, and preparation of case report forms.

Upon completion, students will be able to organize, enter, and review clinical research data.

Course Hours Per Week: Class, 3. Semester Hours Credit, 3.

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. Describe the coordination and organization of subject data for a clinical research project.
- b. Describe various data collection and data capture procedures.
- c. Assist in the design of data collection forms.
- d. Review data collection forms for completeness and accuracy.
- e. Assist in the collection of pertinent data for a specified research publication.
- f. Describe means of data presentation in listings, tables and graphs.

OUTLINE OF INSTRUCTION:

- I. Describe the coordination and organization of patient data for a clinical research project
 - A. Describe the clinical data management process for a typical clinical trial.
 - B. Discuss the elements of a data management plan.
 - C. Identify the different types of case report forms
 - D. Describe appropriate database design and its development
- II. Describe various data collection and data capture procedures
 - A. Discuss various schemes and methods of data collection
 - B. Describe alternate methods of randomization and documentation procedures; identify appropriate methods for specific situations
 - C. Discuss various methods for data capture.
 - D. Identify alternate methods of data entry and describe situations where each method would be applicable
- III. Assist in the design of data collection forms

- A. Identify relevant data and outcome parameters
 - B. Describe methods to capture baseline and follow-up data
 - C. Identify methods used to determine acceptable limits of "normal"
 - D. Develop appropriate closed-end questions to capture unambiguous data
- IV. Review data collection forms for completeness and accuracy
- A. Describe the advantages and disadvantages of single entry versus double entry
 - B. Identify electronic and optical data entry technology and its appropriate application
 - C. Describe data validation methods and the role of database definition in validation
 - D. Computerized checks, data edit reports and appropriate methods for data correction
 - E. Common errors and omissions on case report forms
 - F. Describe the function of quality assurance as it relates to the clinical data management
- V. Assist in the collection of pertinent data for a specified research publication
- A. Describe the basic principles of coding dictionaries and their function
 - B. Describe the appropriate method for handling expedited safety reporting for investigational drugs and devices
 - C. Describe the appropriate method for handling safety reporting for marketed drugs and devices
 - D. Describe the content of periodic update reports to the IRB
 - E. Describe the structure and content of an Investigators' Brochure and identify the appropriate methods for keeping investigators informed of relevant new data
 - F. Identify the structure and content of an integrated study report filed with a regulatory agency in support of a request for marketing approval
 - G. Describe the structure and content of a paper prepared for peer-reviewed journal publication of clinical research data
- VI. Review research data for subject safety
- A. Review patient case report forms and data listings and identify instances of deviation from the approved study protocol
 - B. Review patient case report forms and data listings and identify subjects who received concomitant medication, or experienced concurrent illness during the study, or had secondary diagnoses
 - C. Review patient case report forms and data listings and identify subjects who died or experienced serious adverse events, or withdrawals from the study due to adverse events
 - D. Review patient case report forms and data listings and identify subjects with significant (as defined in the protocol and analysis plan) deviations from a defined normal limit in laboratory parameters
- VI. Generate a final study report
- A. Describe regulatory requirements for a final study report
 - B. Discuss required elements of a final study report
 - C. Generate draft sample final study report

REQUIRED TEXTBOOKS AND MATERIALS:

No textbook required

SUGGESTED REFERENCES, PERIODICALS, AND VISUAL AIDS:

Rondel, R. K., Varley, S. A., & Webb, C. F., Eds. *Clinical Data Management*. John Wiley & Sons, 1993.

Spilker, Bert. *Guide to Clinical Trials*. Lippincott-Raven, 1996.

STATEMENT FOR STUDENTS WITH DISABILITIES:

Students who require academic accommodations due to any physical, psychological, or learning disability are encouraged to request assistance from a disability services counselor within the first two weeks of class. Likewise, students who potentially require emergency medical attention due to any chronic health condition are encouraged to disclose this information to a disability services counselor within the first two weeks of class. Counselors can be contacted by calling 686-3652 or by visiting the Student Development Office in the Phail Wynn Jr. Student Services Center, room 1309.