

**CTR 120**  
**RESEARCH PROTOCOL DESIGN**

**COURSE DESCRIPTION:**

Prerequisites: CTR 130

Corequisites: None

This course introduces the student to the scientific development of research protocols and their key elements. Topics include the differentiation between research design types, rules for writing protocols, ethical considerations relative to research protocols, and the correct preparation of data collection forms. Upon completion, the student will be able to identify the primary components of protocols and effectively develop a protocol draft. 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. Discuss the scientific approach taken in the development of a research protocol.
- b. Identify the key elements that must be addressed in a research protocol.
- c. Differentiate between the various types of research designs and concepts, including the protocol elements used in each design.
- d. Discuss the ethical considerations and issues related to the development of research protocols.
- e. Identify the differences between prospective, retrospective, and combination types of clinical trials.

**OUTLINE OF INSTRUCTION:**

- I. Discuss the scientific approach taken in the development of a research protocol
  - A. Describe the overall process of clinical research development
  - B. Define the classifications of clinical trial designs in Phases I-V
  - C. Discuss the regulatory requirements for protocol development as specified in the FDA regulations and ICH guidelines
  - D. Develop appropriate research hypotheses specific for each phase of research
- II. Identify the key elements that must be addressed in a research protocol
  - A. General information (e.g., title, sponsor, monitor, etc.)
  - B. Background information including a synopsis of the properties of the investigational product
  - C. Study objectives and purpose

- D. Study design
  - E. Selection of subjects and rules for subject withdrawal
  - F. Study procedures and treatment of subjects
  - G. Description of efficacy methods and assessment parameters
  - H. Description of safety assessment parameters
  - I. Detailed description of the statistical methods to be used in analyzing the study data
  - J. Statement concerning direct access to source data and documents
  - K. Description of quality control and quality assurance methods
  - L. Statement of ethical concerns related to the study including methods of obtaining informed consent
  - M. Description of data handling methods and record keeping requirements
  - N. Indemnification statement, insurance requirements and financial arrangements with the investigator, if not found elsewhere
  - O. Statement outlining the sponsor's publication policy
  - P. Protocol amendments, if necessary
- III. Differentiate between the various types of research designs and concepts, including the protocol elements used in each design
- A. Describe various types of research designs including randomized trial, parallel design, crossover design, etc.
  - B. Describe the ways in which bias is controlled in a clinical trial including control, randomization, and blinding
  - C. Discuss the various types of control groups including no control, placebo control, and active control
  - D. Discuss the various ways to randomize for a clinical trial
  - E. Discuss the various ways to blind a clinical trial (open label, single blind, double blind, triple blind)
- IV. Discuss the ethical considerations and issues related to the development of research protocols
- A. Ethical principles consistent with GCPs (Good Clinical Practices) and Federal regulations
  - B. Scientifically sound study hypothesis and treatment procedures
  - C. Rights of the study subject
  - D. Foreseeable risks and unexpected events
  - E. IRB approval and the informed consent process
  - F. Unblinding rules and procedures
  - G. Scientific misconduct
- V. Identify the differences between prospective, retrospective, and combination types of clinical trials

**REQUIRED TEXTBOOKS AND MATERIALS:**

No required textbook.

**SUGGESTED REFERENCES, PERIODICALS, AND VISUAL AIDS:**

Friedman L. M., Furberg C. D., & DeMets, D. L. (1998). *Fundamentals of Clinical Research* (3<sup>rd</sup> ed). New York: Springer-Verlag Inc.

Hulley, S. B., Cummings, S. R., Browner, W. S., Grady D., Hearst, N., & Newman, T. B. (2001). *Designing Clinical Research*. (2<sup>nd</sup> ed.). Philadelphia: Lippincott Williams and Wilkins.

**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.