CTR 120 Research Protocol Design

COURSE DESCRIPTION:
Prerequisites: CTR 130 and CTR 220
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.

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. Discuss the scientific approach taken in the development of a research protocol
2. Identify the key elements that must be addressed in a research protocol
3. Differentiate between the various types of research designs and concepts, including the protocol elements used in each design
4. Discuss the ethical considerations and issues related to the development of research protocols
5. 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-IV
   C. Discuss the regulatory requirements for protocol development as specified in the FDA regulations, ICH guidelines, and SPIRIT guidelines
   D. Develop appropriate research hypotheses specific for each phase of research
   E. Define clear research objectives and select appropriate endpoints to measure study outcomes
   F. Conduct a review of existing scientific literature to gather background information and justify a research rationale

II. Identify the key elements that must be addressed in a research protocol
   A. Describe general information (e.g., title, sponsor, monitor, etc.)
   B. Study summary, schedule of events, and study rationale
   C. Background information including a synopsis of the properties of the investigational product, discussion of important literature and data, applicable clinical context and epidemiological background
   D. Assessment of potential risks and benefits
   E. Study objectives, endpoints, design, and scientific rationale

F. Study population, inclusion/exclusion criteria, screen failures, strategies for recruitment and retention, and participant discontinuation/withdrawal
G. Description of study intervention including dosing and administration procedures
H. Measures to minimize bias, including randomization and blinding
I. Study assessments and procedures, including efficacy assessments, safety and other assessments, and definition of adverse events and serious adverse events
J. General statistical considerations
K. Monitoring and quality considerations, including safety oversight, clinical monitoring, quality assurance and control, protocol deviations, data handling and record keeping, study discontinuation and closure
L. Regulatory, ethical and study oversight considerations, including informed consent process, confidentiality and privacy, publication and data sharing, conflict of interest policy

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. Compare and contrast observational studies with experimental designs, emphasizing their complementary roles in the research process
    C. Analyze case studies to illustrate the application of different trial designs in clinical research
    D. Discuss emerging trends and innovations in clinical trial methodology, such as adaptive trial designs, and their implications for protocol development
    E. Describe the ways in which bias is controlled in a clinical trial including control, randomization, and blinding
    F. Discuss the various types of control groups including no control, placebo control, and active control
    G. Discuss the various ways to randomize for a clinical trial
    H. 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. Explain ethical principles consistent with GCPs (Good Clinical Practices) and Federal regulations
    B. Address the importance of formulating scientifically sound study hypotheses and treatment procedures
    C. Discuss and understand the rights of the study subject
    D. Evaluate foreseeable risks and unexpected events, emphasizing the importance of risk management and mitigation strategies
    E. Describe the role of Institutional Review Board (IRB) approval and the informed consent process in safeguarding participants' rights
    F. Identify unblinding rules and procedures to maintain study integrity and minimize bias
    G. Address issues related to scientific misconduct

V. Identify the differences between prospective, retrospective, and combination types of clinical trials

A. Evaluate the strengths and weaknesses of each type of study design in addressing specific research questions and hypotheses
B. Analyze case studies to illustrate the application of different trial designs in clinical research
C. Compare practical considerations, such as cost, time, and resource constraints associated with prospective, retrospective, and combination types of clinical trials

REQUIRED TEXTBOOK AND MATERIAL:

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