CTR 220 Research Site Management

COURSE DESCRIPTION:

Prerequisites: CTR 115
Corequisites: None

This course introduces the student to elements involved in implementing and managing a clinical trial from the perspective of the research site staff/team. Topics include the identification and evaluation of sites and investigators, on-site budget management, and the coordination of subject participation. Upon completion, students should be able to demonstrate the principles and practices of effective research site management.
Course Hours Per Week: Class, 3. Lab, 3.
Semester Hours Credit, 4.

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. Coordinate an identified clinical research project
2. Apply regulatory, legal, and governing parameters within a clinical research project
3. Plan and prepare research budgets and contracts
4. Recruit, enroll, and retain study subjects
5. Participate in planning, preparation, and conduct of monitoring visits
6. Manage research sites
7. Plan, prepare, and conduct compliance audits
8. Identify and exhibit professional and behavioral skills required of the site-based research professional

OUTLINE OF INSTRUCTION:

I. Coordinate an identified clinical research project
   A. Develop an overall plan for a specified clinical research project
   B. Develop a detailed plan for each stage of the clinical research project
   C. Describe the lines of communication needed between project team members and clinical trial management
   D. Describe the decision-making process for accepting and conducting a research project
   E. Describe the use, design, and importance of set timelines in a well-coordinated research project
   F. Develop study goals and deadlines for clinical research trials

II. Apply regulatory, legal, and governing parameters within a clinical research project
   A. Identify the function, activities, and responsibilities of an Institutional Review Board
   B. Describe the requirements for membership on an IRB according to the Code of Federal Regulations, Title 21 (21 CFR 56.107)
   C. Describe how IRB records are maintained and retained
   D. Describe the IRB submission process and identify the standard review criteria used by an IRB
   E. Define “expedited review criteria”

F. Describe the communication responsibilities between the investigator and the IRB
G. List the eight basic elements of an informed consent form according to Good Clinical Practice (GCP) and Federal regulations and develop a sample consent form
H. Define study file record retention and requirements
I. Evaluate an informed consent form for the eight basic elements
J. Define the contractual relationships in a clinical research project or study
K. Construct a study document checklist
L. Explain how to complete a form FDA-1572
M. Identify the elements needed in a current curriculum vitae
N. Identify the regulatory documents needed prior to shipping investigational supplies
O. Assemble a sample regulatory packet for a clinical research project or study
P. Describe the regulatory, patent and legal considerations in protocol design
Q. Describe scientific misconduct and its consequences

III. Plan and prepare research budgets and contracts
A. Describe the process involved in the development of a research study budget
B. Perform the routine calculations associated with the costs of a clinical research trial
C. List and analyze the budget components for a specified clinical trial relative to cost effectiveness
D. Assist in the calculations of an overall research project budge, including personnel costs, overhead, and profit margin
E. List and identify the types of clinical research sites including academic medical centers, medical research sites, and site management organizations, etc.
F. Identify the problems that can commonly occur between clinical research sites and Sponsors/Contract Research Organizations
G. Describe the role and responsibility of a clinical research investigator and coordinator in the development of a research contract

IV. Recruit, enroll, and retain study subjects
A. Monitor dosage modifications and treatment calculations for compliance
B. Identify and report adverse drug reactions according to study guidelines and reporting requirements
C. Update essential document binders, study files, and manuals with new studies, amendments, and closure notices
D. Complete source documentation and case report forms in compliance with the protocol before review by the clinical research monitor
E. Develop programs to ensure quality control and assurance
F. Review protocol participation with subjects, including procedures and study changes
G. Obtain informed consent from study participants
H. Prepare and maintain required records and follow-up on protocol subjects
I. Collect specimens for submission to central collection laboratories
J. Coordinate subject participation according to established protocols
K. Describe the ethical considerations involved in human experimentation
L. Discuss the identification and reporting of safety events in a clinical trial

V. Participate in planning, preparation, and conduct of monitoring visits
    A. List the roles and responsibilities of the site, study coordinator, and investigator relative to subject data documentation and verification
    B. List the most common errors made in source documentation
    C. List the most common errors made in case report forms
    D. Differentiate between an adverse event and a serious adverse experience
    E. Describe the process for reporting adverse events and serious adverse experiences
    F. Discuss the regulatory criteria utilized in the conduct of a research study
    G. List the requirements/guidelines set by the FDA for facilities participating in clinical trials

VI. Manage research sites
    A. Outline the basic procedures and tasks needed to implement a clinical study
    B. List the considerations in estimating study costs and a site budget
    C. List the qualifications for the investigator, study coordinator, and other site personnel in conducting research in Phase I, Phase II, and Phase III clinical trials
    D. Develop a sample procedure for the management of a research site, including recruiting, budgeting, and timelines
    E. Define the responsibilities and roles of key personnel participating in the management of a research site
    F. Describe the regulatory documents required of a research site
    G. Describe the databases, logs, and files utilized in the maintenance of a study site
    H. Differentiate between the roles of a monitor and the site in the preparation, maintenance, and submission of required reports

VII. Plan, prepare, and conduct compliance audits
    A. Name the regulatory bodies that have the authority to inspect a site
    B. List entities that can be subject to a FDA inspection
    C. Identify other entities that may conduct on-site inspections
    D. List the types of inspections conducted by the FDA, and explain why each type would be conducted
    E. Discuss aspects of study conduct that may be evaluated during an inspection, and identify the areas to be evaluated within each aspect
    F. List the responsibilities of the research site for an anticipated inspection
    G. List the responsibilities of the sponsor or monitor for an on-site inspection
    H. Develop a site checklist of items to be reviewed and/or verified prior to an inspection
    I. Discuss the guidelines used in dealing with FDA auditors relative to the following areas: patient confidentiality, data accessibility, investigator control of the study, gift offers, volunteering information, affidavit signatures, and financial information
    J. Describe an Establishment Inspection Report (EIR) and identify the parties who receive or have access to the report
    K. Describe a form FDA 483 and state how if differs from an EIR List and discuss the outcomes of the types of follow-up actions that can occur after an inspection
    L. Discuss who can be penalized for significant deficiencies and the possible sanctions

VIII. Identify and exhibit professional and behavioral skills required of the site-based research professional
   A. Describe technical skills required for site-based research professionals
   B. Describe soft skills required for site-based research professionals
   C. Discuss professional development for site-based research professionals

REQUIRED TEXTBOOK AND MATERIAL:

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