# 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-

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 progr(o)-6.6 exhibe(n)2.2 (it)7.9d( )( t)-5.9
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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.