CTR 150 Research Fieldwork I

COURSE DESCRIPTION:

Prerequisites: CTR 130 and CTR 220
Corequisites: None

This course provides supervised work experience and observation in a clinical research setting. Emphasis is on the enhancement of professional skills and the practical application of curriculum concepts research setting. Upon completion, students should be able to apply research theory effectively to clinical research practices. Course Hours Per Week: Lab, 15. Semester Hours Credit, 5.

LEARNING OUTCOMES:

The student will demonstrate the ability to apply, in a research setting, basic cognitive and practical knowledge and skills in the areas of:

1. Clinical research project coordination and site management
2. The role and responsibilities of a Clinical Trials Research Associate as a member of the clinical research team at the investigational site or for the pharmaceutical/medical device industry or in a contract research organization
3. Regulatory, legal, and governing parameters as they impact a specific clinical research project
4. Understanding of and proper utilization of research and medical terminology
5. Planning and preparing research budgets and contracts
6. Identification, recruitment and enrollment of an investigator and a study site
7. Recruitment, enrollment and retention of study subjects
8. Collection and evaluation of research data for completeness, compliance, and accuracy
9. Planning and preparing for a compliance audit
10. Professional appearance and attitude and respect others rights and values
11. Reconciliation of personal and professional goals with supervisor's objectives and policies
12. Effective and timely workplace behaviors consistent with the role and responsibility of a Clinical Trials Research Associate student

OUTLINE OF INSTRUCTION:

I. Observation of clinical research activities at the fieldwork site(s)
II. Completion of selected clinical research planning activities
III. Completion of selected ongoing clinical research activities
IV. Completion of selected clinical research compliance evaluation activities
V. Completion of other assignments as designated by the site(s), supervisor(s), and faculty
VI. Closure with the site's clients and supervisor

REQUIRED TEXTBOOK AND MATERIAL:

No textbook required.

SUPERVISOR'S RESPONSIBILITIES:

A. The supervisor will orient the student to the facility, including identifying other disciplines involved in the clinical research process at the specific site.

B. The supervisor will arrange for a quiet place to provide feedback to the student on an individual basis, ensuring privacy and confidentiality.

C. The supervisor will identify one project that the student can observe for at least two sessions, so that the student can adequately accomplish their fieldwork assignments.

D. The supervisor will provide the opportunity for the student to observe and participate in a clinical trials research project.

E. Investigator's site experiences may include, but not be limited to, recruitment and enrollment of human subjects, the informed consent process, IRB review, attending study initiation meetings, planning and conducting study visits, study data collection, responding to CRF queries, budget planning.

F. Pharmaceutical company or contract research organization experiences may include, but not be limited to, clinical research management, budget planning, site selection process, participating in investigator meetings, auditing clinical research sites, packaging of clinical supplies, preparation of CRF queries.

STUDENT'S RESPONSIBILITIES:

A. Students are responsible for confirming their fieldwork with the clinical site supervisor at least one week prior to the scheduled time to determine hours, dress code, materials needed, location of the site facility and directions to the initial meeting place.

B. During the first session, students should review their individual objectives and assignments of the fieldwork experience with their supervisor.

C. The student will identify the specific type of clinical research project management in place at the specific fieldwork site and identify the roles of specific disciplines involved in the coordination of clinical research projects.

D. The student will receive information from the site supervisor regarding:
   i. The pharmaceutical drug or medical device that is the subject of the clinical research project
   ii. The known effects of the pharmaceutical drug or medical device, both beneficial and adverse
   iii. The phase of development in which the product is currently being researched
   iv. The regulatory status of the product
   v. The protocol design and objectives of the study
   vi. Members and roles of the clinical research team

E. The student will observe the supervisor while interacting in meetings, collecting relevant data, and performing study-required tasks.

F. During the clinical research investigational site rotation, the student will observe and participate in, as appropriate, human subject recruitment and enrollment (including the informed consent process), data collection and forms completion, clinical supply inventory, and other administrative responsibilities related to the clinical research project.

G. During the clinical research industry site rotation, the student will observe and participate in, as appropriate, clinical research planning meetings, monitor site visits, source document and case report form review, evaluation of compliance to the clinical research protocol, clinical supply packaging and inventory reconciliation, and other administrative responsibilities related to the clinical research project.