CTR 250 Research Fieldwork II

COURSE DESCRIPTION:

Prerequisites: CTR 130 and CTR 220

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.

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),