

CTR 150
RESEARCH FIELDWORK I

COURSE DESCRIPTION:

Prerequisites: CTR 130, CTR 220, and BIO 169

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.

COURSE OBJECTIVES:

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

- a. Clinical research project coordination and site management.
- b. 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.
- c. Regulatory, legal, and governing parameters as they impact a specific clinical research project.
- d. Understanding of and proper utilization of research and medical terminology.
- e. Planning and preparing research budgets and contracts.
- f. Identification, recruitment and enrollment of an investigator and a study site.
- g. Recruitment, enrollment and retention of study subjects.
- h. Collection and evaluation of research data for completeness, compliance, and accuracy.
- i. Planning and preparing for a compliance audit.
- j. Professional appearance and attitude and respect others rights and values.
- k. Reconciliation of personal and professional goals with supervisor's objectives and policies.
- l. 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.

STATEMENT FOR STUDENTS WITH DISABILITIES:

Students who require academic accommodations due to any physical, psychological, or learning disability are encouraged to request assistance from a disability services counselor within the first two weeks of class. Likewise, students who potentially require emergency medical attention due to any chronic health condition are encouraged to disclose this information to a disability services counselor within the first two weeks of class. Counselors can be contacted by calling 686-3652 or by visiting the Student Development Office in the Phail Wynn Jr. Student Services Center, room 1309.

RESEARCH FIELDWORK I GUIDELINES

Supervisor's Responsibilities

1. The supervisor will orient the student to the facility, including identifying other disciplines involved in the clinical research process at the specific site.
2. The supervisor will arrange for a quiet place to provide feedback to the student on an individual basis, ensuring privacy and confidentiality.
3. 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.
4. The supervisor will provide the opportunity for the student to observe and participate in a clinical trials research project.
 - a. 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.
 - b. 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

1. 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.
2. During the first session, students should review their individual objectives and assignments of the fieldwork experience with their supervisor.

RESEARCH FIELDWORK I OBJECTIVES

1. 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.
2. The student will receive information from the site supervisor regarding:
 - The pharmaceutical drug or medical device that is the subject of the clinical research project.
 - The known effects of the pharmaceutical drug or medical device, both beneficial and adverse.
 - The phase of development in which the product is currently being researched.
 - The regulatory status of the product.
 - The protocol design and objectives of the study.
3. The student will observe the supervisor while interacting in meetings, collecting relevant data, and performing study-required tasks.
4. 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.
5. 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.

Fieldwork I Student Assignment

Students have been instructed to complete their assignments as “homework” on their own time, so as not to interfere with their learning experience. However, some time to interact with clinical research team members will be necessary to complete their assignments. The Fieldwork I assignments are as follows:

Clinical Research Investigational Site Rotation

1. Students are required to complete a daily journal and experience checklist describing their experiences and level of involvement.
2. Students are required to outline the informed consent process for a prospective study participant and critique the informed consent document used in a specific trial, identifying the required elements of the informed consent and other elements included in the selected document.

Clinical Research Industry Site Rotation

1. Students are required to complete a daily journal and experience checklist describing their experiences and level of involvement.
2. Students are required to identify the current members of the project team, describe each member’s responsibilities and outline the monitoring plan for a specific clinical research project.