

### Overview



The Clinical Research Associate Training Program (CRATP) component is unique and the first such initiative in the country. It addresses the absence of minorities from clinical trials. The low participation of minorities leaves unanswered questions such as the appropriate use of some medications and medical devices among these missing groups. The Center will train minority nurses as clinical research associates (CRA's). The CRA will not only have the skills to monitor and manage clinical trials, but also interact with the community to increase their knowledge and understanding of and participation in clinical trials. Thus, the purpose of the post-baccalaureate CRA Training Program is to increase the number of minority CRA's in the State of Louisiana, especially in the Greater New Orleans Metropolitan Area to increase minority participation and retention in clinical trials.

### Course Information

The Post-baccalaureate Clinical Research Associate Training Program consists of two parts. The first component is didactic. The student is required to attend 15 weekly 3 hour classes for a total of 45 hours. This didactic course provides students an orientation and total overview of the class, 11 classes of didactic instruction, and four testing dates. Information covered in Part I includes the Drug Developing Process, Good Clinical Practice (GCP), Federal Regulations and the monitoring. Courses are offered in a semi-formal interactive format, which allow students with a full-time job to complete the courses while continuing to work. Upon satisfactory completion of the didactic component of the program, students complete the NIH and CITI: Patient Safety modules. Upon receipt of these certificates the student advances to a hands-on preceptorship experience. The clinical experiences are held at six collaborative clinical research sites, which offer experiences with CRO's, pharmaceutical firms and clinical facilities. The Hands-on Practicum operationalizes classroom content and provides a systematic approach to the management of clinical trials research. The clinical experience allows the participant to work side-by-side with other clinical research associates, clinical research coordinators, research managers and expert in the field to develop and monitor plans, source documents, complete Case Report Forms, and Standard Operating Procedure Requirements according to the federal government guidelines. The students will experience:

- A minimum of 96 contact hours with a professional member of a clinical trial study, such as the CRA, CRC, manager, budget manager, data analyst, etc., and
- Interactive case studies simulating the role of a CRA/CRC.

The clinical hours are to be completed within 12 weeks. Both components together yield a total of 132 hours. CE awards are given on didactic component of the course.

### CRATP Course Objectives

Upon successful completion of the course, the learner will:

1. Identify policies, procedure, and resources to fulfill the role of the CRA/CRC.
2. Discuss regulatory requirements, ethical issues, Good Clinical Practices involved with clinical trials.
3. Describe current principles and practices in medical research from product path starting with discovery and ending with marketing approval.
4. Demonstrate the ability to coordinate clinical trials to assure compliance to study protocols.
5. Provide education about trials to patients and families, and acting as liaison between the patient/family and the health team
6. Discuss recruitment and screening for potential study participants.
7. Apply critical thinking techniques in managing clinical trial studies.

### **CRATP Clinical Objectives**

1. Complete a clinical experience that reinforces CRA/CRC didactic content.
2. Apply CRA/CRC skills to ongoing trials involving patients, devices, pharmaceuticals and procedure.

3. Participate in all compliance requirements, i.e. noting IRB requirements, preparing reports to agencies that sponsor clinical trials, etc.,

Clinical Research Training Program Application Process (download)

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