Richmond University Medical Center

Research Department

Richmond University Medical Center, Research Department is looking for dynamic candidates who are pursuing a career in the medical field, especially in clinical and/or research areas.

Although it is voluntary, learning clinical research requires full exposure to the life cycle of a research study and hands on experience, which we provide, free, for volunteer's intellectual growth.

In our program, our study staff are titled "Clinical Research Coordinator (CRC)". They have been receiving hands-on training in medical terminology and a basic understanding of medicine. Strong computer skills are required. After proper training, they will be able to carry out assigned study responsibilities.

At RUMC, we are actively involved in investigator-initiated and industrysponsored clinical research studies. Most of our industry sponsored clinical research studies are in COVID, Cardiology, Pulmonary, GI and Oncology and other therapeutic areas. Also, the volunteers will have the opportunity to design and conduct their own research studies) and with the opportunity to publish.

We require our volunteer CRC's to work onsite 5 days a week (<u>between Mon-Fri, 8:00 AM to 3:00 PM</u> or <u>9:00 AM to 4:00 PM</u>) for 35 hours per week and minimum 12 months of full time commitment.

As a voluntary research coordinator, they will be receiving free lunch every day and \$2,000 stipend after completion of every 6 months of fulltime assignments. There is no other direct benefit, however it is a wonderful opportunity for graduates to have hands-on experience in clinical research operation and patient management.

After completion of the training period, most of our trainees were admitted to prestigious medical schools in the country or hired by drug companies, CRO or academic research organizations. Many of our foreign medical graduates were accepted into the medical residency programs in the USA and abroad.

Educational Requirement:

- College Senior, College Graduate (BA/BS/RN).
- Medical Graduate (MD/MBBS), Postgraduate (MS/PhD).

Primary Responsibilities:

- Responsible for working under the guidance of the Principal Investigator (PI) and Sub-Investigators (Sub-I) and the Administrative Director, Department of Clinical Research (DCR), to participate in the planning, implementation and overall direction of clinical research projects conducted on behalf of sponsors at the RUMC DCR.
- The CRC is required to perform study procedures, to generate, evaluate, review and record study data, to transcribe source data to case report forms, to liaise with sponsor personnel, to maintain a high level of professional expertise through familiarity with the study protocol, investigator's brochure, and related study materials, and to participate in project team meetings.
- The CRC is required to travel among all the study sites including DCR, hospital and medical offices where studies are conducted. The CRC assists the PI and Sub-I in conducting clinical studies in compliance with applicable regulations and GCP guidelines.

Specific Duties:

- Actively involved in recruitment and screening activities of research subjects to evaluate their eligibility for a clinical study.
- Assists in the administration of informed consent to research subjects under the supervision of the Principal Investigator (PI) and sub-investigator (Sub-I).
- Prepare and submit the regulatory document to the Sponsor, Institutional Review Board (IRB), and other agencies. Obtain and maintain IRB approval of the study/studies. Maintains a regulatory study file or binder for each study protocol.
- Develops a high level of familiarity and knowledge of the study protocol and flow chart of study procedures. Develops a strategy for implementing study procedures in compliance with the study protocol.
- Performs study procedures (*e.g.,* start intravenous lines, venipuncture, obtain biological specimen samples, obtain ECG recordings, vital signs, safety assessments, etc.) as required by study protocol.
- Records study data in the source documents. Evaluates and reviews study data to ensure accuracy and completeness. Transcribes study data from source documents to sponsor designated case report forms or records data for remote data entry (EDC system) if applicable.
- Assists PI or Sub-I with gathering and recording and reporting of adverse events and serious adverse events of the patients to the sponsor, IRB and / or FDA.