Position Description: Retrospective Clinical Research Coordinator I

The Durham VA Medical Center (DVAMC) is looking for a Retrospective Clinical Research Coordinator to oversee and manage select retrospective research studies conducted by the principal investigator, Dr. Stephen Freedland, and his associates in his urology and cancer research lab. Responsibilities include management of IRB and regulatory paperwork, compilation and documentation of data, and management of projects/personnel. The CRC will be responsible for studies involving chart abstraction, claims-based data, and data derived from natural language processing techniques. This position will report to the Clinical Research Manager.

Critical Element 1

Oversee and coordinate select retrospective clinical research performed by the PI:

- Lead project-specific kickoff meetings with staff to review project goals, timelines, and responsibilities
- Develop requirements for creation of proper databases, cohort identification, and data exports
- Act as liaison between researchers and local staff including programmers and data technicians to query and abstract data
- Coordinate with study sponsors, contractors, other PIs and research team members as part of sponsored or multi-PI studies
- Meet with the Clinical Research Manager weekly to review progress of clinical research
- Attend other meetings and give oral report on updates to studies as necessary

Critical Element 2

Maintain all IRB and regulatory paperwork for select retrospective clinical research performed by the PI at the DVAMC:

- Work with a regulatory assistant to develop, prepare and submit VA-specific protocol, informed consent form, HIPAA authorization, protocol amendments, and other related documents for initial review by the IRB
- Work with a regulatory assistant to prepare and submit yearly request for continuing approval of open protocols, audits, adverse event reports, and any other IRB-required submissions
- Maintain study binders with all IRB related documents and correspondence
- Develop Standards of Procedure for each study
- Screen documents for completeness and compliance with protocol and appropriate regulations; investigate incomplete, inaccurate or missing documents to ensure accuracy and completeness of data collected and follow-up with subjects as needed
- Ensure self and staff adhere to VA privacy and security requirements

Critical Element 3

Supervise study personnel involved in data abstraction and entry including employees, students, residents, and fellows:
• Supervise study personnel, residents, fellows, and student involved in select retrospective clinical research across multiple centers
• Hire and train new study personnel as needed
• Assist with initiation and maintenance of WOC and VINCI status at the DVAMC for self and other personnel
• Approve timecards, conduct performance reviews, troubleshoot technical problems, respond to procedural questions

Critical Element 4

Work with IMR to facilitate contracts for all clinical research performed by the PI at the DVAMC:

• Ensure CRADA and statement of work language is consistent with other regulatory documents including data use agreements, consents, and protocols
• Coordinate with sponsoring group to develop SOP, obtain CRADA approval, maintain appropriate study document, CRFs, and organize site visits
• Assist with budget developments, contracts, and invoicing

Critical Element 5

Collaborate with Clinical Research Manager and other CRCs and work effectively with all team members

• Provide input on clinical research projects related to budget, timelines, scheduling, staffing, and other relevant issues
• Train additional team members as necessary to ensure protocols are followed. Maintain training and delegation logs
• Make decisions about day to day operations related to specific study protocols. Make recommendations about program development, employee performance and larger scale operations of the research group

Non-critical Elements

• Work with colleagues and VA personnel to expedite transfer of large amounts of data for storage in relational databases
• Coordinate with multiple other centers around the country to teach them about data abstraction and help in data management and to facilitate merging of their data with our database
• Perform other related duties incidental to the work described herein.

The above statements describe the general nature and level of work being performed by individuals assigned to this classification. This is not intended to be an exhaustive list of all responsibilities and duties required of personnel so classified.

Required Skills:

Requires an organized, task oriented, deadline sensitive individual with a B.A./B.S. degree and 1-2 years of relevant experience. Graduate education may be considered in lieu of work experience. Candidates must be able to deal diplomatically and professionally with
administration, faculty, clinical and lab personnel, and subjects. Demonstrated leadership, professional initiative, teamwork abilities, strong interpersonal relationship skills, excellent written and oral skills, Windows, Microsoft Word, Excel, Access, editing, and proper telephone etiquette skills are required for this position. Incumbent should possess professional knowledge of clinical research sufficient to provide training and guidance to others in the clinic. Prior experience with clinical research, data collection, database technologies, FDA regulations, and HIPAA considerations is preferred. Salary will be commensurate with experience level.

To Apply: Please go to https://freedlandlab.recruitee.com/ and select “Apply for this Job” under the Retrospective Clinical Research Coordinator description.

Employees work for the Institute for Medical Research and will have an appointment at the Durham VA Medical Center. Please visit www.imr.org for more information about employee benefits. We are an equal-opportunity employer.