Duke University School of Nursing
Job Description
HR Job Title: Clinical Research Coordinator
Job Code: 1201
Job Level: 52
Record ID/title picker: 1931
Updated: 8/31/22

Occupational Summary
The proposed project will expand the Duke Sickle Cell Disease Implementation Consortium (SCDIC) by adding a Biobank will generate longitudinal comparative data needed to tailor medication treatment to a patient's phenotype and genetic profile. Studies will be accomplished through the collection of biospecimens, survey, and abstracted medical record data from existing participants enrolled in Duke's SCDIC Research Registry and add new enrollees.

Position is funded for five years

Work will be on site for specimen pick up and transport to lab, subject recruitment and team meetings. There will be some opportunities for remote work.

Supervisor
This position reports to the School of Nursing Research Practice Manager with a dotted line to the study Principal Investigator.

Work Performed

Operations:
Recognizes when typical agreements (MTAs, CDAs, DUAs, DTAs, etc.) are necessary and alerts appropriate parties. Knowledgeable in regulatory and institutional policies and processes; applies appropriately in study documentation, protocol submissions, and SOPs. May train others in these policies and processes. Prepares for and provides support for study monitoring and audit visits, including support for the reviewer. Addresses and corrects findings. Maintains participant level documentation for all studies, including those that are complex in nature (e.g., procedural and interventional studies) and/or require access to the Duke EHR. Employs strategies to maintain retention rates. Evaluates processes to identify problems with retention. Employs and may develop strategies to maintain recruitment rates and evaluate processes to identify problems. Escalates issues. Screens, consents, and enrolls participants for complex studies (e.g., procedural and interventional studies). Develops or helps develop SOPs. Independently employs simple procedures for picking up a collected specimen and transporting biospecimens. Maintains study level documentation for all studies, including those that are complex in nature (e.g., procedural and interventional studies). Schedules participants for research visits. Prepares necessary documents, equipment, supplies, etc. Conducts and documents non-complex visits and scripted testing or interviews. May manage participant payment. Leads meetings that are multidisciplinary, including those with complex objectives. May train or oversee others in all aspects of study operations.

Ethics:
Recognizes known potential adverse events, identified in the protocol or investigator brochure, and reports to study team. Conducts and documents consent for participants for all types of studies,

including those that are complex in nature and/or require any orders in Maestro Care. Develops consent plans and documents for participants in a variety of studies. Develops and submits documentation and information for IRB review. Communicates with the IRB staff and reviewers and handles issues appropriately. May train or oversee others in carrying out all policies, procedures and activities needed to assure study meets all ethical standards.

Data:
Enters and collects data. Develops data entry or collection SOPs or tools. May provide oversight or training to study team members collecting or entering data. Independently corrects and documents incomplete, inaccurate or missing data for non-complex studies. Follows SOPs for quality assurance. Runs summaries and reports on existing data. Recognizes and reports security of physical and electronic data vulnerabilities. May develop or review RDSPs for multiple study protocols. Maps a protocol's data flow plan including data capture, storage, transfer, management, quality, and preparation for analysis (may include data from EDCs, EHR, mobile apps, etc.). Independently uses and implements technology to enhance productivity or process. May train or oversee others in all aspects related to study associated data .

Science:
Assists with or contributes to the development of funding proposals. Assists with simple literature searches. Under guidance, develops sections of protocols for simple studies (e.g., registries, survey studies). Demonstrates a basic understanding of the elements of research study designs. Contributes to the development of scientific publications or presentations. Serves as an author on poster presentations or publications.

Study and Site Management:
Prepares for, coordinates, and actively participates in site visits. Communicates effectively with sponsors and/or CROs. Records participant accrual information and consent documentation for non-complex studies in clinical research management system. Uses clinical research management system and its reports to manage all protocol activities, including minimum footprint, SIP counsel, and all aspects of maintaining current protocol information. Collects appropriate information to determine whether the study team's participation in a specific trial is feasible. May make recommendations. For studies with complex supplies or equipment, ensures that there are ample supplies and that equipment is in good working order. May forecast staffing needs. Ensures that studies are conducted in compliance with institutional requirements and other policies. Follows, and may develop or implement, protocol-specific systems and documents including process flows.. Prepares studies for closeout and document storage. May train or oversee others in study and site management.

Leadership:
Proactively seeks opportunities to add relevant skills and certifications to own portfolio. Keeps current with research updates by attending key external offerings (i.e. Research Wednesday, RPN, events outside of Duke, etc.) and applies the learned material to the job. May disseminate information to others. Serves on committees and workgroups internal to Duke or externally in therapeutic area of research. Demonstrates interpersonal skills to get work done efficiently. Recognizes and escalates organizational issues that could be optimized to improve research process. Demonstrates resilience and is adaptive to change. Uses advanced subject matter expertise in the therapeutic area or clinical research to solve problems. Communicates effectively with others, regardless of reporting relationship, to accomplish shared work objectives.

Required Qualifications at this Level
Education/Training
1.Completion of a Bachelor's degree 2. Completion of an Associates degree plus a minimum of two years relevant experience (e.g., research, clinical, interaction with study population, program coordination)

Experience
Experience in clinical research or with the study population preferred.

Skills
Can easily use computing software and web-based applications (e.g., Microsoft Office products and internet browsers).

Work will be on site for specimen pick up and transport to lab, subject recruitment and team meetings. There will be some opportunities for remote work.

Supervisor
This position reports to the School of Nursing Research Practice Manager with a dotted line to the study Principal Investigator.