Duke University School of Nursing
Job Description
HR Job Title: Clinical Research Coordinator
Working Title: Clinical Research Coordinator
Job Code: 1201
Job Level: 52
Updated: 7/23/2024

Occupational Summary
This position includes work on studies conducted within the School of Nursing Clinical Research Unit and the Oncology Clinical Research Unit.

Work in the School of Nursing CRU consists of multisite management for a mobile health app intervention for cancer survivors who received a bone marrow or stem cell transplant with posttraumatic stress disorder (PTSD) symptoms. Primary responsibilities will be subject recruitment, multisite project management, data collection, regulatory, and data entry. Critical skills include leadership and drive, attention to detail, problem solving, flexibility, oral and written communication, and teamwork.

Work within the Oncology CRU consists of research to compare the well-being of patients and caregivers of patients receiving home vs standard care after autologous hematopoietic stem cell transplant. Additionally, work on a research study to determine whether the carbohydrate prebiotic (dietary supplement) known as galacto-oligosaccharide (GOS) can modulate the microbiome and help prevent graft-versus host disease (GVHD) after allogeneic stem cell transplant. Primary responsibilities include screening, recruitment and enrollment of eligible participants. Assist in managing data, documenting deviations and adverse events, reporting data, and preparing for monitoring visits. Manage databases, oversee device inventory, and ensure proper device management. Provide training to team members on research assessments, sample collection, and device setup. Create individual participant study calendars and schedule study visits. Maintain effective communication between research and clinical teams.

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

Work Performed
<u>Operations:</u>
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, IRB 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 non-complex (e.g., questionnaire, data registry, scripted) studies outside of the EHR.
Follows SOPs and strategies to recruit, enroll, and retain research subjects. May develop or help develop SOPs.

Employs and develops strategies to meet or exceed recruitment rates and revise processes to fix problems. Escalates issues.
Screens participants for complex studies (e.g., procedural and interventional studies).
Maintains study level documentation for all studies, including those that are complex in nature (e.g., procedural and interventional studies).
May train or oversee others. Schedules participants for research visits (including those requiring EHR access).
Prepares necessary documents, equipment, supplies, etc.
Works closely with the Principal Investigator(s) and study team to recruit, screen, and enroll participants for studies.
Conducts and documents non-complex visits and scripted testing or interviews.
Follow procedures and documentation of participant payment and patient care expenses in a timely fashion. Monitor financial study milestones and report appropriately. Coordinate with financial teams and participate in budget development and closeout.
Lead team meetings and facilitate healthy communication between staff.
Ensure good communication across multiple study teams and research sites, and mentor staff to improve communication strategies.
Maintain compliance with institutional requirements and policies.
Maintain appropriate study-level documentation including, but not limited to, regulatory binders, enrollment logs, training of key study personnel, and delegation of authority logs

Ethics:
Ensures that multiple study teams/research program team members are appropriately identifying and documenting adverse event information.
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. May train or oversee others.
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.
Prepares and submits documents needed for regulatory and safety reporting to sponsors and other agencies.

Data:
Enters and collects data for research projects.
Develops data entry or collection SOPs or tools. May provide oversight or training to study team members collecting or entering data.
Oversees the process of QA, data corrections, and queries used within multiple study teams/the research program, including creating and using QA protocols, queries, summaries, and reports.
Recognizes trends and recommends strategies to improve processes or retrain staff.
Serves as an expert data corrections, queries, and quality assurance resource, including liaising with and being knowledgeable about other related resources at Duke.
Assists multiple study teams in developing protocols that include strategies and processes to ensure data security and provenance.
Recommends and leads implementation of improved processes, policies, and systems to ensure data security and data provenance. 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.

Recognize and report vulnerabilities related to security of physical and electronic data.
Assist in investigating incomplete, inaccurate or missing data and documents to ensure accuracy and completeness of data.

Science:
Independently conducts literature searches and reviews. Contributes to the development of scientific publications or presentations. Serves as an author on poster presentations or publications.

Study and Site Management:
Uses clinical research management system and its reports to manage research participants' activities, including minimum footprint, calendars, tracking/marking financial milestones, and all aspects of study visits. May train others.
For studies with simple supplies or equipment, ensures that there are ample supplies and that equipment is in good working order.
For multiple study teams, ensures that studies are conducted in compliance with institutional requirements and other policies.
Oversees implementation of operational plans across multiple study teams or sites.
Prepares studies for closeout and document storage.

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 internally to Duke or externally in therapeutic area of research.
Navigates processes and people involved in Duke clinical research, demonstrates the organizational awareness, and has the interpersonal skills necessary to get work done efficiently.
Develops and implements solutions that work within the existing leadership or organizational structure.
Demonstrates resilience and is adaptive to change.
Trains others to communicate effectively within teams.
Facilitates resolution of issues associated with teams or communication.
Serve as primary liaison with sponsors, study team personnel, and PI for assigned studies. Collaborate and communicate with other study team personnel as required.
Escalate complex questions and issues appropriately to others.

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

Experience
Experience in multi-site research study and grant management preferred.

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