Duke University School of Nursing
Job Description
HR Job Title: Clinical Research Coordinator
Working Title: Clinical Research Coordinator
Job Code: 1201
Job Level: 52
Record ID/title picker: 1566
Updated: 8/20/2021

Occupational Summary

Position includes work on different projects. One project is a multisite sickle cell disease study. Primary responsibilities will be to organize, manage and lead study team meetings with six sites, collaborate with the data coordinating center (Duke Clinical Research Institute, DCRI), and assist the sites with recruitment strategies. Another project is community engaged research looking at health, stress, and resilience among young adult Hispanic and Latino immigrants in the Unites States. Main responsibilities on this project include scheduling and conduct of remote study visits, data collection and entry, specimen collection pick up and lab processing, SOP development, and prepare and submit regulatory documentation. Another project involves working with Latinx adolescents and key stakeholders to determine facilitators of and barriers to receiving evidence-based psychotherapy for depression. Primary responsibilities include conduct of study interviews and focus groups, data entry, recruitment, screening, and prepare and submit regulatory documentation.

Supervisor

This position reports directly to the Assistant Research Practice Manager for the School of Nursing Clinical Research Unit and will work directly with the PI's and research teams.

Work Performed

1.Clinical research 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. May train others. 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. May train or oversee others. Employs strategies to maintain retention rates. Evaluates processes to identify problems with retention. May train or oversee others. Employs and may develop strategies to maintain recruitment rates and evaluate processes to identify problems. Escalates issues. May train or oversee others. Screens participants for complex studies (e.g., procedural and interventional studies). May train or oversee others. Develops or helps develop SOPs. May train or oversee others. Collects, prepares, processes, ships, and maintains the inventory of research specimens, primarily those requiring complex procedures. May train or oversee others. 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. 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.

2. Ethical and participant safety considerations:

Identifies all AEs and determines whether they are reportable. Collaborates with the PI to determine AE attributes, including relatedness to study. May train or oversee others. 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. May train or oversee others. 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.

3. Data management and informatics:

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. Ensures accuracy and completeness of data for all studies, including those that are complex in nature. Recognizes data quality trends and escalates as appropriate. May develop tools for, and train others in, data quality assurance procedures. 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.). May train or oversee others. Learns and uses new technology when required. 6.Study and site management. Participate in sponsor-required training.

4. Science:

Assists with or contributes to the development of funding proposals. Independently conducts literature searches and reviews. Demonstrates a basic understanding of the elements of research study designs.

5. Study and site management:

Uses clinical research management system and its reports to manage research participants' activities, calendars, tracking/marking financial milestones, and all aspects of study visits. Uses required EMR functionalities to manage participants and study visits. May train others. 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. May train others. For studies with simple supplies or equipment, ensures that there are ample supplies and that equipment is in good working order. 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. May train or oversee others. Prepares studies for closeout and document storage. May train or oversee others.

6. 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. 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. 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.

Maintain Duke and project specific training requirements. Develop solutions to proactively ensure study team members' compliance with training requirements.

7. Communication:

Communicate concerns clearly and in a professional manner. Participate in study team meetings. Respond to routine questions related to study protocol and refer more complex questions to others as appropriate. Communicate and coordinate with other study personnel as required for study implementation and routine problem resolution.

Required Qualifications at this Level
Education/Training

Requires completion of an associate's degree plus a minimum of two years relevant research experience or completion of Bachelor's degree.

Experience

Experience in research and regulatory preferred.

Skills

1. Can easily use computing software and web-based applications (e.g., Microsoft Office products and internet browsers).
2. Must be fluent in Spanish.
3. Basic phlebotomy skills.
4. Excellent Communication skills and the ability to work with a multi-disciplinary research team.