Duke University School of Nursing
Job Description
HR Job Title: Clinical Research Coordinator
Job Code: 1201
Job Level: 52
Record ID/title picker: 2129
Updated: 5/09/23

Occupational Summary

The purpose of this position is to assist the Principal Investigator in designing, implementing, and overseeing a 5-year, multi-site research study. The coordinator will independently prepare research and training materials, IRB applications, and oversee data collection, management, and quality control. The hired candidate will oversee ongoing recruitment and retention efforts, as well as qualitative and quantitative data collection activities. The person in this position will work with people from a variety of backgrounds and cultures. The ideal candidate for this position will have experience planning, designing, and implementing multi-site research projects, will be organized, and can work independently and as part of a group. The candidate should also have experience managing and conducting quality control on large, mixed methods data sets. The hired candidate will conduct trainings for staff and community partners and will supervise staff and students. A strong understanding of public health research design is required for this position.

Supervisor

This position reports to the Research Program Leader for the RISE Lab.

Work Performed
Operations:

For complex scenarios, recognizes when agreements are necessary within the research program. Facilitates the process by coordinating with study teams and appropriate Duke offices. 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. 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.

Ethics:

Identifies all AEs, and determines whether or not 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. Prepares and submits documents needed for regulatory and safety reporting to sponsors and other agencies. May train or oversee others.

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. 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. Independently uses and implements technology to enhance productivity or process. May train or oversee others.

Science:

Assists with or contributes to the development of funding proposals. Demonstrates a basic understanding of the elements of research study designs. Provides some contribution to scientific publications or presentations (no authorship).

Study and Site Management:

As directed, attends or schedules site visits. 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.

Leadership:

Works with the manager to understand areas of opportunity and develop a training plan. Takes training courses and applies the knowledge and skills. May also train others in the skills learned. 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.

Perform other related and requested duties incidental to the work described herein.

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
Preferred qualifications: Master's degree in a related field (public health, social sciences) preferred Prefer experience working or doing research with LGBTQIA people Prefer someone with a working knowledge of data management software (e.g. Redcap) Previous supervisory experience preferred Previous experience working on a large mixed methods research study.

Skills
Ability to plan and coordinate research data collection
Ability to work independently, problem solve, and multi-task
Working knowledge of how to conduct public health research