Duke University School of Nursing
Job Description
HR Job Title: Clinical Research Coordinator

Job Code: 1201
Job Level: 52
Record ID/title picker: 2128
Updated: 5/09/23

Occupational Summary

The purpose of this position is to assist the Research Program Manager in overseeing regulatory and data management tasks for studies in the RISE lab. The candidate for this position will organize and communicate data cleaning notes to study statisticians, write data management plans, create data reports for the Pl and co- investigators, and maintain tracking databases to track participant progress in the study. The protocol coordinator will also assist the research program manager in overseeing regulatory matters across studies. The position will assist with IRB submissions, check informed consent forms, and make sure that enrolled participants meet all eligibility criteria.

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. Under supervision, prepares for study monitoring and audit visits. Develops or helps develop SOPs. May train or oversee others. Participates in study team meetings.

Ethics:

Under supervision, for non-complex studies (e.g., survey studies and registries), develops and submits documentation and information for IRB review. 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:

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:

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. 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:

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
Has a working knowledge of LGBTQ health research Proficiency in Microsoft Excel and Access Experience managing large datasets
Quality control experience in a research setting

Skills
Has a working knowledge of LGBTQ health research Proficiency in Microsoft Excel and Access Experience managing large datasets Quality control experience in a research setting Data/Information Analysis/Management - Ability to monitor and collect data/information as required by research or program protocol. Ability to input data/information into databases with limited management as required by protocol. Ability to perform statistical analysis. Ability to observe and report trends in data/information. Ability to produce estimates using established guidelines, tools, methods, and general statistical practice.

Ability to multi-task, remain organized, and a strong attention to detail Ability to work independently and problem solve