Duke University School of Nursing
Job Description
HR Job Title: Clinical Research Coordinator (Spanish-speaking)
Working Title: Clinical Research Coordinator (Spanish-speaking)
Job Code: 1201
Job Level: 52
Record ID/title picker: 2119
Updated: May 18, 2023

Occupational Summary

This position includes 100% effort to work on research studies focused on addressing the needs of English- and Spanish-speaking patients with traumatic brain injury (TBI) and family caregivers during the transition home from acute hospital care. The candidate selected must be fluent in reading, writing, and comprehending in English and Spanish. The research is funded by the National Institutes of Health. This team member will work closely with the Principal Investigator and study team members to implement study protocols with main roles to include screening, recruiting, conducting study visits, data collection, data entry, and data analysis. This position is fully remote apart from occasional study visits and recruitment events which may be conducted within the community and will require travel within the research triangle area. Additionally, this position may require work in the evenings and/or weekends on a rotating basis.

Supervisor

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

Work Performed

1. Operations:

Daily screening of the electronic medical record of patients hospitalized with TBI to determine eligibility to participate.

Conduct longitudinal data collection and lead individual interviews with participants in English and Spanish.

Translation and backtranslation of study materials from English to Spanish.

Coordination with other study team members and DUHS healthcare providers.

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.

Employs and may develop strategies to maintain recruitment rates and evaluate processes to identify problems. Escalates issues.

Screens participants for complex studies (e.g., procedural and interventional studies).

Develops or helps develop SOPs. Maintains study level documentation for all studies, including those that are complex in nature (e.g., procedural and interventional studies).

Conducts and plans for complex study visits. May train staff.

Leads meetings that are multidisciplinary, including those with complex objectives.

2.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.

Assists with the development of consent plans and documents for participants. Develops and submits documentation and information for IRB review. Communicates with the IRB staff and reviewers and handles issues appropriately.

3.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. Follows required processes, policies, and systems to ensure data security and provenance. In addition, recognizes and reports security of physical and electronic data vulnerabilities.

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.

Runs and maintains accurate documentation of randomization scheme.

4. Science:

Independently conducts literature searches and reviews. Synthesizes and categorizes literature obtained from searches and reviews. 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.

5.Study and site management:

Records participant accrual information and consent documentation for complex behavioral intervention 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. May train others.

For studies with simple supplies or equipment, assists with ensuring 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.

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 organizational awareness, and has the interpersonal skills necessary to get work done efficiently.

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.

7. Miscellaneous

Complete and process subject payment forms. Follow Duke procedures in regard to collecting Data Disclosure forms and requirements around SSN# storage and payment processing.

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 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 working on randomized controlled trials is preferred.

Experience working with health-related care of patients or clinical research studies is preferred.

Skills
Must be fluent in Spanish and English (reading, writing, and comprehension).

Can easily assist with qualitative and quantitative data collection and analysis.

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

Proficiency with use of REDCap, Qualtrics, and Nvivo is preferred.