Duke University School of Nursing
Job Description
HR Title: Clinical Research Coordinator
Working title: Clinical Research Coordinator
Job Code: 1201
Job Level: 52
Record ID/Title picker: 1357
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Occupational Summary

This position will work with a team of two Co-Principal Investigators on a telehealth and digital health study. This study includes work with healthcare providers and patients with diabetes and hypertension. The research is funded by National Institutes of Health (NIH), National Institute of Nursing Research (NINR). This team member will work closely with the Principal Investigators and study team members to implement study protocols with main roles to include IRB and regulatory maintenance, screening, recruiting, conducting study visits, data collection, data entry, and data monitoring. The candidate will need to learn how to use mobile health technologies and mobile apps that will be given to patients (i.e., phone-tethered glucometer and blood pressure cuff, wireless scale and smartphone apps). This will include ordering devices and helping patients with device setup and minor trouble shooting. Study visits and recruitment events will occur remotely and in-person at Duke Health sites, which may require some travel within the research triangle area.

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 team.

Essential Duties

1. Operations
    a. Responsible for study screening, consenting and recruitment of participants.
    b. Knowledgeable in regulatory and institutional policies and processes.
    c. Prepare documents, equipment, or supplies for research visits. Conduct and document visits and protocol- specific testing/interviews according to study protocol, operational plans of clinical departments, and Standard Operating Procedures (SOPs) for all types of studies independently. May train others.
    d. Independently maintain subject level documentation for all studies.
    e. Participate in the development of recruitment flyers, study forms, questionnaires and study operating procedures (SOPs), as appropriate.
    f. Develop, manage and implement recruitment and retention strategies. Employ strategies to maintain recruitment and retention rates and identify issues related to recuitment and retention rates.
    g. Responsible for maintaining all study 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 electronic health record.

h. Responsible for regulatory maintenance of studies.
i. Responsible for all IRB reporting, including new study submissions, deviations, amendments, adverse events, renewals, personnel changes, and final progress reports.
j. Develop, submit, and maintain IRB documents such as consent forms, protocols, and recruitment materials.
k. Schedule and conduct participant study visits.
l. Independently conduct and document consent within the approved IRB process including documentation of consent and storage of consents for all studies.
m. Monitor study timeline and tasks.
n. Familiarity with the use of technologies and software necessary for study operations.
o. May manage participant payment.
p. Recognizes when typical agreements (MTAs, CDAs, DUAs, DTAs, etc.) are necessary and alerts appropriate parties.
q. Participates in study team meetings.
r. Screening of Duke electronic health record to determine protocol eligibility.
s. Coordination with other study staff and DUHS healthcare providers.

2. Data
    a. Ensure all data collected is captured, collected and stored according to IRB and Duke required practice.
    b. Develops data entry or collection SOPs or tools. May provide oversight or training to study team members collecting or entering data.
    c. Independently uses and implements technology to enhance productivity or process. May train or oversee others.
    d. Take part in or lead closeout and document storage activities.
    e. Assist with the development of protocol-specific systems and documents including process flows, training manuals, standard operating procedures, and case report forms.
    f. Recognize when data agreements (ie, data use, data transfer, material transfer) are needed and provide appropriate documentation for the drafting and execution of agreements.
    g. May develop tools for, and train others in, data quality assurance procedures.
    h. Map protocol data flow. Predict areas of vulnerability for a protocol's data flow plan. Determine areas where data provenance may be compromised. May be responsible for determining solutions to vulnerabilities related to security of data and data provenance.
    i. Investigate incomplete, inaccurate, or missing data/documents to ensure accuracy and completeness of data; follow and develop, or assist with development of, SOPs for data quality assurance.
    j. Adhere to processes and run queries, summaries, and reports to monitor the quality of data. May develop QA processes and oversee the creation and use of queries, summaries, and reports for quality assurance purposes. Responsible for recognizing trends related to data quality and escalating as appropriate.
    k. Analyze and/or interpret qualitative interview data.

3. Ethics
    a. Maintain familiarity with the ethical conduct of research and safeguards needed when conducting research with vulnerable populations. Understand that the safety of research participants is a priority.
    b. May develop or assist with the development of documents related to safety and security (e.g., Research Data Security Plans, Data Safety Monitoring Plans, Conflict of Interest). Coordinate or assist with the coordination of efforts of external monitoring boards.
    c. Assist with the development of Research Data Storage Plans and update as appropriate.
    d. 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.
    e. Communicates with the IRB staff and reviewers and handles issues appropriately.
    f. Prepares and submits documents needed for regulatory and safety reporting to sponsors and other agencies.
    g. Communicate to research participants, both orally and written, the difference between clinical activities and research activities, and the risks and benefits of study participation, in all study documents and research participant communications. May recognize when patients are having difficulties with this distinction. Make recommendations regarding how to improve communications to help participants and staff understand the distinction.
    h. Use required processes, policies, and systems to ensure data security and data provenance. Recognize and report vulnerabilities related to security of physical and electronic data; suggest and implement solutions to vulnerabilities related to security of data and data provenance.
    i. Develops consent plans and documents for participants.
    j. 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.

4. Science
    a. Assist PI with abstract, poster, and manuscript preparations, submissions and report writing, as appropriate.
    b. Conduct literature reviews independently and assist with the development of research proposals or protocols.
    c. Contributes to the development of scientific publications or presentations and serves as an author on poster presentations or publications.

5. Study and Site Management
    a. Follows, and may develop or implement, protocol-specific systems and documents including process flows.

b. Uses clinical research management system and its reports to manage research participants' activities, calendars, tracking/marking financial milestones and all aspects of study visits.
c. Keep study documents and materials up to date on the study electronic folder.
d. Create and maintain filing systems and study logs for study.
e. Maintain study compliance with institutional requirements and other policies (i.e., NIH Public Access Policy, ct.gov, Research Data Storage Plans, Social Media Policy, etc.).
f. Records participant accrual information and consent documentation for non-complex studies in clinical research management system.
g. 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.
h. For studies with complex supplies or equipment, ensures that there are ample supplies and that equipment is in good working order.
i. Develop protocol-specific systems and documents including process flows, training manuals, standard operating procedures, and case report forms.

6. Leadership
    a. Maintains Duke and projects specific training requirements.
    b. May serve as mentor to other staff.
    c. Assist research colleagues in identifying efficiencies and improving process.
    d. 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.
    e. Navigates processes and people involved in Duke clinical research, demonstrates the organizational awareness, and has the interpersonal skills necessary to get work done efficiently.
    f. Serves on committees and workgroups internal to Duke or externally in therapeutic area of research.
    g. Uses advanced subject matter expertise in the therapeutic area or clinical research to solve problems.
    h. Communicates effectively with others, regardless of reporting relationship, to accomplish shared work objectives.

7. Miscellaneous
    1. Complete and process subject payment forms. Follow Duke procedures in regards to collecting Data Disclosure forms and requirements around SSN# storage and payment processing.
    2. Perform other related and requested duties incidental to the work described herein.

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

Minimum of two years relevant research experience. A Bachelor's degree may substitute for two years required experience.

1. Experience working on investigator initiated studies is essential.
2. Experience in regulatory study maintenance is essential.
3. Experience working with mobile health technology and mobile apps is preferred.
4. Experience working within EPIC electronic health records system is preferred.

Skills

5. Can easily use computing software and web-based applications (i.e. Microsoft Office products and internet browsers).
6. Can assist with qualitative data collection and analysis.
7. Proficiency with use of REDCap is preferred.
8. Strong organizational skills essential.