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: 1927
Updated: 8/25/2022

Occupational Summary

This position includes work on research studies that focus on cancer prevention with a particular focus on mobile health intervention research. The research is funded by National Institutes of Health. Tasks include implementing study protocols with main roles to include screening, recruiting, conducting study visits, data collection, data entry, informed consent process and data analysis. Study visits and recruitment events will be varied and may be conducted electronically as well as within the community.

Supervisor

This position reports directly to the Assistant Research Practice Manager for the School of Nursing Clinical Research Unit.

Essential Duties

1. Operations
    a. Responsible for study screening and recruitment of participants.
    b. Independently maintain subject level documentation for all studies.
    c. Train others to conduct and document visits and protocol-specific testing/interviews.
    d. Participate in the development of recruitment flyers, study forms, questionnaires and study operating procedures (SOPs), as appropriate.
    e. Employ strategies to maintain recruitment and retention rates and identify issues related to recuitment and retention rates.
    f. Responsible for maintaining all study level documentation including regulatory binders, enrollment logs, delegation of authority logs, OnCore entry, etc.
    g. Responsible for all IRB reporting, including new study submissions, deviations, amendments, adverse events, renewals, personnel changes, and final progress reports.
    h. Develop, submit, and maintain IRB documents such as consent forms, protocols, and recruitment materials.
    i. Schedule and conduct participant study visits.
    j. Independently conduct and document consent within the approved IRB process including documentation of consent and storage of consents for all studies.
    k. Organize study meetings and take minutes
    l. Monitor study timeline and tasks
    m. Assist the PI with study management.

2. Data
    a. Collect required study data which could include surveys, interviews, questionnaires, diagnostic tests, clinical data from medical records and other sources and data capture via mobile devices. Data collection may be conducted in person, via phone, or electronically.
    b. Ensure all data collected is captured, collected and stored according to IRB and Duke required practice.
    c. Provide study enrollment counts to PI's when requested, as well as counts for how many subjects have completed each time point in the study.
    d. Coordinate with financial teams and participate in budget development as appropriate.
    e. Take part in or lead closeout and document storage activities.
    f. Assist with the development of protocol-specific systems and documents including process flows, training manuals, standard operating procedures, and case report forms.
    g. Recognize when data agreements (ie, data use, data transfer, material transfer) are needed and provide appropriate documentation for the drafting and execution of agreements.
    h. Coordinate and assist with database maintenance, data migration and data entry.
    i. May develop tools for, and train others in, data quality assurance procedures.

3. Ethics
    a. Be familiar with the ethical conduct of research and safeguards needed when conducting research with vulnerable populations.
    b. Assist with the development of Research Data Storage Plans and update as appropriate.
    c. Identifies all AEs and determines whether or not they are reportable. Collaborates with the PI to determine AE attributes, including relatedness to study.

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. Assist collaborators and statisticians in understanding data discrepancies.
    d. 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. Ensure that all study materials used are the ones approved by the IRB.
    b. Keep study documents and materials up to date on the SED drive.
    c. Assist PIs in proofing new study materials and suggesting modifications in wording or order, providing feedback based on previous contact with research subjects and materials.

d. Create and maintain filing systems and study logs for study.
e. Monitor financial study milestones and report accordingly.
f. Oversee the training of key personnel on study specific duties.
g. 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.).

6. Leadership
    a. Maintain training requirements and develop solutions to proactively ensure study team members' compliance with training requirements.
    b. May serve as mentor to other staff.
    c. Assist research colleagues in identifying efficiencies and improving process.
    d. Uses advanced subject matter expertise in the therapeutic area or clinical research to solve problems.

7. Communication

    a. Alert PI to potential issues where it is not clear how to proceed (i.e., situations that are out of the ordinary)
    b. Communicate with other study personnel as required for study implementation and routine problem resolution.
    c. Write and speak clearly in a variety of settings and styles to convey messages and ideas effectively.
    d. Participate in study team meetings and conference calls.

8. 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, bachelor's degree preferred.

Experience

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

Skills

1. Can easily assist with quantitative data collection.

2. Can easily use computing software and web-based applications that link to mobile devices (e.g. Microsoft Office products and internet browsers.)
3. Proficiency with use of REDCap and Qualtrics.