Duke University School of Nursing
Job Description
HR Title: Clinical Research Coordinator (Part-time)
Working title: Clinical Research Coordinator (Part-time)
Job Code: 1201
Job Level: 52
Record ID/Title picker: 2544
Updated: 11/20/2024

Occupational Summary

This part-time position will work with the Principal Investigator and team on a community-based study. This study includes work with healthcare providers and children 11-17 years of age with concussion and their families. The research is funded by National Institutes of Health (NIH), National Institute of Neurological Disorders and Stroke (NINDS). This team member will work closely with the Principal Investigator 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. This role will also encompass project oversight. The candidate will need to engage with children and families over a 12-month period. This will include obtaining multiple time point biological samples and surveying patients. Study visits and recruitment events will occur remotely or in-person at the concussion clinic or participant home sites, which may require some travel within the research triangle area.

Supervisor

This position reports directly to the Research Practice Manager for the School of Nursing Clinical Research Unit and will work directly with the PI 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, biological sample collection and coordination with Duke Molecular Physiology lab, 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, including those that are complex in nature (e.g., procedural).

h. Responsible for regulatory maintenance of studies.
i. Responsible for IRB reporting, including new study submissions, deviations, amendments, adverse events, renewals, personnel changes, and final progress reports.
j. Responsible for coordinating with study sites regarding updates on IRB, enrollment/recruiting, study protocol and regulatory documentation.
k. Develop, submit, and maintain IRB documents such as consent forms, protocols, and recruitment materials.
l. Schedule and conduct participant study visits.
m. Independently conduct and document consent within the approved IRB process including documentation of consent and storage of consents for all studies.
n. Monitor study timeline and tasks.
o. Familiarity with the use of technologies and software necessary for study operations.
p. Manage participant compensation/payment.
q. Recognize when typical agreements (MTAs, CDAs, DUAs, DTAs, etc.) are necessary and alerts appropriate parties.
r. Participate in study team meetings.
s. Coordination with other study staff and study site providers.

2. Data
    a. Ensure all data collected is captured, collected and stored according to IRB and Duke required practice.
    b. Develop data entry or collection SOPs or tools. May provide oversight or training to study team members collecting or entering data.
    c. Independently use and implement 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. Have a clinical understanding of concussion care protocols and electronic health 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. Coordinate or assist with the coordination of efforts of external monitoring boards.
    c. Assist with the development of Research Data Storage Plans (Duke Research Lifecycle) and update as appropriate.
    d. Identify all AEs and determine whether or not they are reportable. Collaborates with the PI to determine AE attributes, including relatedness to study. May train or oversee others.
    e. Communicate with the IRB staff and reviewers and handle issues appropriately.
    f. Prepare and submit documents needed for regulatory and safety reporting to sponsors and other agencies.
    g. Communicate to research participants and their families, 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. Develop consent plans and documents for participants.
    j. Conduct and document 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. May assist with simple literature searches.
    c. Contribute to the development of scientific publications or presentations and serve as an author on poster presentations or publications.

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

b. Use 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. Record participant accrual information and consent documentation for non-complex studies in clinical research management system.
g. Use 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, ensure 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. Maintain Duke and projects specific training requirements.
    b. May serve as mentor to other staff.
    c. Maintain communication with site sites for project oversight.
    d. Assist research colleagues in identifying efficiencies and improving process.
    e. Proactively seek opportunities to add relevant skills and certifications to own portfolio. Keep current with research updates by attending key external offerings (i.e. Research Wednesday, RPN, events outside of Duke, etc.) and applys the learned material to the job.
    f. Navigate processes and people involved in Duke clinical research, demonstrate the organizational awareness, and have the interpersonal skills necessary to get work done efficiently.
    g. Serve on committees and workgroups internal to Duke or externally in therapeutic area of research.
    h. Use advanced subject matter expertise in the therapeutic area or clinical research to solve problems.
    i. Communicate effectively with others, regardless of reporting relationship, to accomplish shared work objectives.

7. Miscellaneous
    a. Complete and process subject payment forms. Follow Duke procedures in regard to collecting documenting payments, data storage requirements and payment processing.
    b. Perform other related and requested duties incidental to the work described herein.

Required Qualifications at this Level
Education/Training

Completion of a bachelor's degree in addition to a Licensed Athletic Trainer (LAT) and Athletic Training certification (ATC) with experience in concussion plus a minimum of two years relevant research experience; OR completion of master's degree in addition to an LAT and ATC, with experience in concussion is preferred.

Experience

1. Completion of a Bachelor's degree; OR 2. Completion of an Associate's degree plus a minimum of two years relevant experience required (e.g., research, clinical, interaction with study population, program coordination); OR 3. Completion of master's degree with experience in concussion is essential.
2. Experience with concussion patients or history of research in concussion or biologic research is essential.
3. Familiarity with concussion clinic operations preferred.
4. Experience working on investigator-initiated studies is preferred.
5. Experience in regulatory study maintenance is preferred.
6. Experience working with healthcare providers is essential.
7. Experience working within EPIC electronic health records system is preferred.
8. Experience interacting with children and families in the context of research is essential.

Skills

1. Strong organizational skills essential.
2. Can assist with data collection and analysis.
3. Proficiency with use of REDCap is preferred.