



Job Description

Title: Clinical Research Coordinator

Description:

The Clinical Research Coordinator recruits, screens and enrolls eligible subjects. Complies with and implements protocol procedures. Monitors follow up visits. Oversees regulatory and administrative details.

Reports to: Manager of Clinical Services

Duties:

The Clinical Research Coordinator will:

- ✓ Collaborate with team members and Sponsors in the development and implementation of clinical trials
- ✓ Screen, recruit, and enroll qualified subjects into clinical trials and monitor their status
- ✓ Provide direct nursing services/procedures/consultation and conduct site visit activities
- ✓ Develop efficient and cost-effective clinical study materials for trial conduct
- ✓ Comply with all SOPs, regulations, and good clinical and ethical practices
- ✓ Collect and accurately record data

Responsibilities:

Specific responsibilities include:

- ✓ Adhering to employee goals, SOPs, regulations, good clinical and ethical practices and protocol procedures
- ✓ Coordinating clinical trials with safety, integrity, and efficiency
- ✓ Ensuring accurate clinical assessment, source documentation, data collection, regulatory file composition, and trial communications with subjects, investigators, and caregivers.
- ✓ Ensuring that all trial activities are carried out in accordance with the protocol
- ✓ Ensuring that the logistical objectives of the clinical trial are met
- ✓ Providing weekend and off-hour coverage, as needed



- ✓ Accounting for all test article and study drug supplies and inventories
- ✓ Gathering data, compiling information, and preparing reports
- ✓ Preparing and submitting trial specific information to the IRB and others, as assigned
- ✓ Assisting with SOP design and development, and quality assurance activities, as assigned
- ✓ Performing other duties as assigned

Qualifications:

The ideal candidate must meet the following minimum requirements (we will consider those with similar experience):

- ✓ Current Minnesota license as an RN or LPN
- ✓ Clinical trial experience
- ✓ Ability to draw blood and process medical laboratory samples
- ✓ Ability to evaluate and triage subjects and to develop and manage nursing care plans
- ✓ Ability to foster a cooperative work environment
- ✓ Thorough understanding of medical terminology, FDA regulations, and GCP guidelines
- ✓ Excellent understanding of project management and clinical research processes
- ✓ Exceptional organizational, interpersonal and communication skills; professional presentation
- ✓ Highly proficient with MS Office (Word, Excel, Access, and PowerPoint), email, internet
- ✓ Advanced understanding of data management and monitoring processes
- ✓ Attention to detail
- ✓ Ability to prioritize and multitask in a sometimes fast paced environments
- ✓ Ability to be productive during slower periods
- ✓ Critical thinking
- ✓ Willingness to cross train with other roles (RAs, Front Desk Coordinator)