spaulding clinical
RESEARCH BEYOND RESULTS

Job Description

Clinical Research Nurse - Basic

SPAULDING CLINICAL aims to be the clinical research organization by which all others are measured. Pioneering in our approach to redefining how the industry perceives and achieves success; passionate in our pursuit of ingenious solutions that mitigate risk; loving in our care for our volunteers, customers and employees; and heroic in our ambitions to ensure the health and safety of people around the globe - Spaulding Clinical is taking ***research beyond results*** to create a marketplace of safer drugs.

Original Date: 27 Oct 2009

Revision Date: 09 Jun 2016

Job Summary:

Responsible for basic nursing activities (such as, but not limited to, Informed Consent documentation, medical history, AE/CM, drug administration/accountability, dose verification) in the conduct of clinical trials with emphasis on the safety and welfare of study participants. Performs the practical activities of clinical studies according to protocol, regulatory requirements, SOPs, scope of practice and current training status.

Essential Duties and Responsibilities:

- With supervision, ensures that clinical trials are conducted according to protocol requirements by utilizing the following techniques & procedures.
- Ensures subject has complete understanding of study-specific Informed Consent Form and that all questions have been answered. Accurately documents and records completion of ICF.
- Obtains and accurately documents structured subject medical, surgical and medication history
- Administers study drug and any other protocol-required medications, while accurately ensuring the 5 Rights of Medication Administration (the right subject, the right drug, the right dose, the right route, and the right time)
- Performs dose verification, assisting other Clinical Research Nurses during dose administration to accurately verify subject identity and dosing labeling, as additional quality check.
- Contributes and is accountable for secure and appropriate storage of all drug supplies after removing from pharmacy.
- Records subject Adverse Events with proper escalation to medical or Charge Staff for evaluation and treatment as warranted.
- Performs additional task list items as delegated and supervised by Charge Staff.
- Reviews Study Specific Trainings and applicable protocols for a thorough understanding of the study procedures, as they apply to their role and ensures that Delegation of Authority/Training Log for each study is completed in a proper and timely manner.

- Keeps abreast of SOPs, Good Clinical Practice (GCP) and ICH guidelines, state and national laws and ethical standards.
- Observes and maintains all HIPAA, OSHA, and Exposure Control regulations and Emergency Response as required by applicable training.
- Creates and maintains accurate records of all protocol activities and events, as delegated and trained.
- Follows progress of volunteers and provides for their care, comfort and safety by attending to their needs during study participation.
- Participates in quality assurance of clinical research projects and initiates the need for same as it impacts on clinical practice.

The Statements made in the job description are intended to describe the general nature and level of work being performed by people assigned to this job. These statements are not intended to be an exhaustive list of all responsibilities, duties and skills required of people assigned to this job.

Skills/Qualifications

- Ability to read, write and interpret the English language.
- Portrays professionalism in all interactions at Spaulding Clinical.
- Good computer skills; inclination to adopt technology to maximize efficiency
- Demonstrates strong analytical, problem solving skills
- Strong written and verbal communication skills.
- Detail oriented, good organizational traits.
- Self-motivated
- Must be results-oriented, multi-tasking, quick learner, respond to the urgent needs of the team, and show a strong track record of meeting deadlines.
- Ability to work beyond normal work hours and various shift availability required.
- Ability to perform and record data entry via computer systems while conducting timed clinical procedures.

Physical Demands:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of the job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Ability to sit, stand, walk, reach with hands and arms, and use hands along with fingers, to handle or feel.
- Ability to lift and/or move up to 25 pounds.
- Specific vision abilities required by this job include clarity of vision both near and far.
- Ability to identify and distinguish colors.

Hazards:

- Potential for exposure to toxic or caustic chemicals
- Potential for exposure to blood borne pathogens

Education and Experience:

- Current RN or LPN License (Graduate Nurses must possess a temporary license in order to work as CRN, and must obtain Wisconsin licensure within 6 months of hire)
- CPR certification required within one year of hire or promotion date
- ACLS certification desirable

Spaulding Clinical Research management has the discretion to hire personnel with a combination of experience and education which may vary from the above listed skills and qualifications.

This is to acknowledge that I have read and understand the above job description. This copy supersedes any others previously distributed. I further understand that Spaulding Clinical may change, add or delete any essential duties and responsibilities described at its discretion with or without prior notice.

Employee Name (Printed) Date

Employee Signature