spaulding clinical
RESEARCH BEYOND RESULTS

Job Description

Nurse Practitioner / Physician Assistant

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: 11 Mar 2011

Revision Date: 20 Apr 2011

Position Reports To: Director of Clinical Operations

Position Supervises: None

Job Summary:

Reviews medical histories and performs comprehensive screening and in-study physical examinations to determine eligibility of research subjects to enroll in clinical trials and monitor the safety of research subjects enrolled in clinical trials. In collaboration with the Principal Investigator, reviews and interprets laboratory results, ECG results, adverse events, and any other activities as directed. Also evaluates initial and ongoing eligibility of volunteers enrolled in the clinical trial. Refers subjects for additional medical care as appropriate and or consults with Principle Investigator.

Essential Duties and Responsibilities:

- Work closely with the Principal Investigator, Clinical Research Nurses, and Research Coordinators.
- Coordinates the subject selection process by assembling and assessing screening results and collaborating with the PI to determine eligibility of a subject for participation in a clinical trial.
- In collaboration with the Principal Investigator, assesses and documents adverse events occurring during the clinical trial, and evaluates for causality and severity.
- Contributes to development of semi-annual and annual reports to the Sponsor. Provides assistance to the PI with protocol submissions and communications to all appropriate Institutional Review Boards and other regulatory authorities.
- Ensures ongoing compliance with protocol requirements. May assist in the development of protocol documents including consent forms, source documents, and other data collection tools, and monitors implementation and compliance.

- Reviews Investigational Drug Brochures, protocols, Case Report Forms (CRFs), consent forms and volunteer information sheets for a thorough understanding of the study drug and procedures.
- Keeps abreast of SOPs, Good Clinical Practice (GCP) and ICH guidelines, state and national laws and ethical standards.
- 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.
- Proficient in performing physical examinations
- Phlebotomy experience preferred
- Excellent at managing multiple work loads
- Demonstrates strong analytical, problem-solving skills
- Strong written and verbal communication skills.
- Detail oriented, good organizational traits.
- Must possess professional knowledge of a wide range of medical/nursing concepts, principles, and practices to perform highly specialized assessments as well as knowledge of anatomy, physiology, pathology, and pharmacology
- 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.
- Excellent computer skills; inclination to adopt technology to maximize efficiency
- 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:

- Graduate from an accredited college or university's nursing or physician's assistant program with a degree and current Wisconsin licensure and/or certification as an Advanced Registered Nurse Practitioner or Physicians' Assistant.
- CPR/BLS is required.

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