spaulding clinical
RESEARCH BEYOND RESULTS

Job Description

Clinical Research Technician

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: 11 Mar 2011

Position Reports To: Director of Clinical Operations

Position Supervises: None

Job Summary:

Responsible for technical procedures and selected study unit activities in the conduct of clinical trials with emphasis on the safety and welfare of study participants. Perform the practical/administrative activities of clinical studies according to protocol, regulatory requirements, and SOPs. This may involve some project related responsibilities in conjunction with the Research Nursing staff.

Essential Duties and Responsibilities:

- With supervision, ensures that clinical trials are conducted according to protocol requirements by utilizing the following techniques & procedures
- Sample management - collection & processing of biological samples for assay storage & shipment including generation of computer labels for lab & drug assay samples
- Record volunteer adverse events with proper escalation to medical or nursing personnel for evaluation & treatment as warranted.
- Perform electronic & diagnostic measurements including electrocardiograms, blood glucose measurements, visual exams, etc.
- Performs & records physical measurements including vital signs, body measurement (height/weight) & pulse oximetry etc.
- Assist in the development of new testing procedures
- Process volunteer identification (photos, badges)
- Provide necessary instructions to research participants
- Assist in meal administration, ensuring the correct meal and correct content is delivered to the correct study participant.

- 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.
- Admits volunteers to Unit and completes admission procedures, reviews House Rules and next day's protocol activities.
- Maintains accurate records of all protocol activities and events, sampling times, special test procedures and adverse events.
- 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.
- Phlebotomy Skills Preferred
- Technical Assessment skills
- Basic Computer Skills
- 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.
- Good 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:

- Associate's degree (A.A./A.S.) in a scientific discipline military medic experience (preferred).
- Nursing assistant or clinical training highly desirable.
- Two years experience performing phlebotomy, performing ECGs, participating in the conduct of clinical trials, and maintaining monitoring equipment preferred.
- Experience as an EMT preferred.
- CPR certification required within one year of hire.

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