
Clinical Research Nurse

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: 04 Sep 2012

Job Summary:

Responsible for study unit activities related to the conduct of clinical trials with emphasis on the safety and welfare of study participants. This may involve some project related responsibilities by coordinating activities for routine studies in compliance with protocol, Standard Operating Procedures (SOPs) and regulatory guidelines from the inception of the protocol throughout the completion of the database lock process.

Essential Duties and Responsibilities:

- 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.
- Assists with health screening, on study and follow-up of volunteers, obtains structured health and drug histories, vital signs, obtains ECGs, EEGs, lung function tests, psychometric tests, collects and processes biological specimens, assists the physicians with physical examinations.
- Admits volunteers to Unit and completes admission procedures, reviews House Rules and next day's protocol activities.
- Administers test compounds as appropriate, makes appropriate observations, collects and processes biological specimens as required by the protocol.
- 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.
- Record and assess volunteer adverse events with further escalation to medical personnel for evaluation & treatment as warranted.
- Contributes and is accountable for a secure and appropriate storage of all drug supplies.

- Ensures effective verbal and written communications inter and intra departmentally in the planning and implementation of volunteer clinical research regimens.
- Develops and implements innovative nursing research interventions that reflect an ability to make discriminating assessments for complex research projects.
- Participates in quality assurance of clinical research projects and initiates the need for same as it impacts on clinical practice.
- Readily accepts responsibility and is accountable for own and delegated activities.

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.
 - Excellent Time Management Skills
 - Proficient at multi-tasking
 - Phlebotomy Skills Preferred
 - 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 and has an inclination to adopt technology to maximize efficiency
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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.
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Hazards:

- Potential for exposure to toxic or caustic chemicals

- Potential for exposure to blood borne pathogens
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Education and Experience:

- Current RN or LPN License
 - CPR certification
 - ACLS certification (preferred)
 - Demonstrated knowledge of "Good Clinical Practices" preferred
 - Excellent communication skills (interpersonal, written, verbal)
 - Strong attention to detail
 - Excellent time management skills
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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.
