
Clinical Research Coordinator

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: 01 Dec 2017
Reports To: Clinical Research Project Manager
Supervises: N/A

Job Summary:

Responsible for study activities related to the conduct of clinical trials with emphasis on the safety and welfare of study participants. Perform project/study management related responsibilities by coordinating activities for Clinical Pharmacology Studies in compliance with protocol, Standard Operating Procedures (SOPs) and regulatory guidelines from the inception of the protocol throughout completion of the database lock process. This involves working closely with all functional areas as well as external providers to ensure consistent high quality study outcomes.

Essential Duties and Responsibilities:

- At study award, responsible for establishing communications with the pharmaceutical sponsor, and initiating study setup.
- Creates a Project Plan for the study and delegates study setup tasks to the appropriate departments and staff.
- Oversees the design and development of the clinical research study, and compiles all setup items into the comprehensive operational plan directory.
- Throughout the study, ensures that all study activities are executed according to the study protocol, regulatory guidelines, and operational plan.
- Reviews Investigational Drug Brochures, Protocols, Case Report Forms (CRFs), and informed consent forms 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.
- Identifies necessary study supplies and orders them through appropriate channels.
- 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.

- 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.
- Provides shift and weekend coverage for in-house studies and follow-up visits.
- 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.
- Directs, supervises and contributes to the development of nursing and technical staff caring for the volunteers.
- Participates in quality assurance of clinical research studies and initiates the need for same as it impacts on clinical practice.
- Reviews professional growth plans developed by direct reports when applicable.
- Participates and collaborates in the presentation of reports and abstracts research proposals while actively involved in pertinent professional organizations.
- 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.
 - Demonstrated ability to lead by example and to encourage team members to seek solutions
 - Excellent planning, organizational, and time management skills
 - Excellent oral, written and presentation 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 and skills; 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.

Hazards:

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

Education and Experience:

- Current RN License preferred, but not required
- CPR certification
- ACLS certification preferred, but not required
- Ability to prepare for CRC certification
- Prior experience in multi-level project helpful
- Demonstrated knowledge of "Good Clinical Practices"

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