spaulding clinical
RESEARCH BEYOND RESULTS

Job Description

Clinical Research Trial 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: 28 Aug 2013

Revision Date: 04Aug2020

Job Summary:

This position reports to the Project Management Office Manager but may also receive delegation of tasks by the Project Manager and Assistant Project Manager (PM/APM). The CRTA focuses on project management set-up, execution, and close-out for study activities related to the conduct of clinical trials with emphasis on the safety and welfare of study participants and adherence to all regulatory needs.

Performs 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.

This role would be best suited to those with experience in one of Spaulding Clinical Research's support departments (but may not have study floor experience) who has shown strength in SOP's, Project Management, and the ability to plan, implement, and track a successful project or an external applicant who has previous clinical research and/or project management experience. Attention to detail and the ability to handle multiple priorities within specific time parameters is a critical part of this job role.

Essential Duties and Responsibilities:

- At study award, responsible for working with PM/APM on tasks, as assigned, to begin study set-up.
- Very familiar with, and able to adhere to details of all Study Management SOPs and Work Instructions.
- Facilitates the design and development of the clinical research study and compiles all setup items into the comprehensive operational plan directory, as directed by PM/APM.
- Throughout the study works closely with the PM/APM and the CRC to ensure 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 and identifies areas that may have a risk for errors or deviations.
- Possesses the ability and knowledge to create and implement mitigations to all identified risks.
- Keeps abreast of SOPs, Good Clinical Practice (GCP) and ICH guidelines, state and national laws and ethical standards.
- Clearly understands the importance and need for Good Documentation Practices, source documentation, and their relation to ALCOA-C.
- Meets with PM/APM and collaborates to help ensure Risk Management and Mitigation Plan is created and completed in order to ensure study-specific training and other trainings for staff are complete, organized, effective, and follow Spaulding Clinical's SOP's and Work Instructions.
- Ensures a thorough understanding and comprehension of all Spaulding's SOP's with relationship to the floor and screening events to ensure they can identify and communicate the difference with those and the protocols.
- Assists with the APM/PM on creating training content and staff resources that are in compliance with protocol and regulatory documents, along with CRC. Ensures appropriate trainings can be put in place to decrease risk of errors in study execution.
- Understands and is competent with Spaulding's E-source system to help ensure data is being collected appropriately and per applicable eCRF guidelines.
- Is available as a resource for floor staff for protocol and study specific questions.
- Escalates any study, subject, or staff concerns/issues to the Project Manager or other clinical manager.
- Participates in quality assurance of clinical research studies and initiates the need for same as it impacts on clinical practice.
- Is present at weekly (or as needed) teleconference with Sponsor and understands how to prepare agendas, as well as take appropriate notes and write meeting minutes.
- Assists the CRC and PM/APM on the creation of procedure plans and other documents such as SST's, AE guidelines, Quick Reference Guides, etc.
- Available for assisting with the Event Schedule creation as directed by the Project Manager and fully responsible for the Staffing Template creation.
- Assist with comparison of study build, Event Schedule, and Data Collection Module (DCM) for form and timepoint accuracy, per protocol
    - Assists with transfer of electronic data between Spaulding Clinical EDC platform and sponsor platform, if needed.
    - Assists with processing subject payments and works with the PM/APM, finance to make sure subjects received them on time.

- Interface with Biometrics, study floor staff, and CRC to assure complete and precise query resolution, as directed
- Can be assigned to projects or duties to support the department as needed
- Able to assist with all special projects or study-specific events as required by protocol.

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, implementation, 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.
- Willing to understand facets of regulatory standards, focus on customer needs, and ensure the success of a project
- 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
- High level of professionalism, ability to interact with staff and focus on both study and staff needs. Knowledge of and ability to adhere to staff's need for confidentiality practices, as well as enforce no-gossiping policy present for Spaulding Clinical staff.

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 or Bachelor's Degree in related field, preferred
- Staff member with minimum of 1 years' experience at Spaulding Clinical Research, preferred for internal promotion
- Prior experience in multi-level project management assistance,
- Demonstrated knowledge of "Good Clinical Practices"
- Experience with prioritizing and finishing competing projects.
- Data entry experience preferred
- Experience dealing with detail-oriented job duties.

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 _____