# Sr. 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: 12 Jul 2018

Revision Date:

## Job Summary:

Responsible for the oversight of designated Clinical Research Coordinator activities related to the conduct of clinical trials with emphasis on Spaulding Clinical's SOP's, regulatory guidelines, quality, and protocol adherence.

Oversee the daily work of designated Clinical Research Coordinators (CRC's) by overseeing adherence to SOP's, Work Instructions, Good Clinical Practice (GCP), FDA regulations, and each individual study protocol. Able to provide prompt and thorough review (with appropriate feedback) on all study documents created by the CRC.

Great familiarity with a variety of the industry concepts, practices, and procedures. Relies on extensive experience and judgment to plan and accomplish goals of high quality outcomes.

Leads and directs the work of the CRC's on his/her team. Responsible (along with CRC) for customer satisfaction in regards to protocol adherence, operational excellence and quality, team cohesiveness, and proper study execution.

Always present for customers (sponsors) by being available for site visits, teleconferences, and able to provide tours. Willing and able to provide excellent customer service for all sponsors, their representatives, CRAs, etc.

Responsible for training those new to the Clinical Research Coordinator role, as an available resource for CRC's on regulatory, SOP, and various Phases of study information/training materials to enhance and fulfill the complex responsibilities needed in the CRC role.

**Essential Duties and Responsibilities:**

- Develops Leadership skills to increase customer and employee satisfaction.
- Aligns self and actions with Goals per business and objectives by:
    - being open and accepting of change,
    - increasing professionalism (colleague relationships, customer service, using time productively, able to appropriately delegate)
    - displaying operational excellence (job knowledge, focus on quality, problem-solver, lack of protocol deviations within CRC Team, task completer)
- Monitors and updates (as needed) Clinical Research Coordinator, Clinical Trial Associate and Clinical Administrative Assistant training course. Plans and coordinates new CRC/CTA/CAA hire training opportunities. Reviews all outputs of CRC/CTA/CAA Trainee for accuracy and provides feedback to create an appropriate learning environment.
- Oversees the design and development of the clinical research studies, via direct observation and coordination with CRC Team. Understands each clinical study well enough to be assigned as “Back-up CRC”.
- Promotes effective intradepartmental relationships; encourages cross-functional cooperation.
- Throughout the study, ensures that all study activities are executed per 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.
- Participates in quality assurance of clinical research studies and initiates the need for same as it impacts on clinical practice.
- 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.
- Initiates and oversees a comprehensive Risk Management exercise and Internal Kickoff Meeting to identify and mitigate study risks.
- 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.
- Provides thorough oversight to all delegated tasks and evaluates input to clinical trial. This oversight would encompass (but not limited to): Pharmacy, Clinical Lab, PK Lab, AE/CM Management, Recruitment, Meals, and Data Management.

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.
- 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.

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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:

- Bachelor’s Degree in Nursing, Healthcare Management or related field, preferred
- Minimum of two years Phase 1 Research Coordinator experience required
- Possesses the leadership skills to effectively direct employees while in a training environment and ability to properly evaluate comprehension and application of material
- ACRP (or equivalent) certification, preferred
- Demonstrated "Good Clinical Practices" and regulatory knowledge

***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