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## Clinical Research Administrative 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.

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Original Date: 04 Jan 2017

Revision Date: n/a

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### Job Summary:

Clinical Research Administrative Assistants oversee projects and duties assigned by their manager and/or Clinical Research Coordinators. They assist in all administrative tasks relevant to a clinical trial start-up, conduction, and close-out. This will primarily revolve around ensuring Regulatory Binder/Trial Master File documents are created, filed, and updated, as needed. Clinical Research Assistants will work alongside the rest of the team, while ensuring assigned duties are completed in a timely, efficient, productive, and organized manner.

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### Essential Duties and Responsibilities:

- Works closely with Clinical Research Coordinators to ensure all aspects of clinical protocols and trials are properly documented.
- Creates and maintains Regulatory Binder and/or Trial Master File (TMF) according to standard protocol and/or sponsor request.
- Creates, quality-checks, and files all study-related regulatory and paper source documents.
- Possesses ability to take on responsibilities (either temporarily or permanently) that need to be developed and managed for a successful study environment. These will be assigned by management as needed.
- Reviews all work periodically with management to ensure accuracy, cost-effectiveness, and sponsor satisfaction remain high priority.
- Able to identify problems that may adversely affect department functionality and either correct the problem or notify the appropriate supervisor.
- Exudes confidence and a positive attitude amongst colleagues.
- Promotes an environment of service excellence, teamwork, and quality care in all interactions with colleagues, sponsors, and subjects.

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.

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### **Skills/Qualifications**

- Ability to read, write, and interpret the English language
  - Demonstrates strong analytical, problem solving skills
  - Strong written and verbal communication skills
  - Detail oriented, robust 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.
  - Strong 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:**

- High School graduate
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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.*

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## Job Description

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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.

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Employee Name (Printed)

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Date

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Employee Signature