spaulding clinical
RESEARCH BEYOND RESULTS

Job Description

Principal Investigator

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: 11 Mar 2011

Position Reports To: General Manager & Senior Vice President of Operations

Position Supervises: None

Job Summary:

As Principal Investigator at Spaulding's Clinical Site, you will be responsible for the overall conduct of the clinical trials conducted here from the signing of the FDA form 1572 throughout the review of the Clinical summaries. In this unique position you will work very closely with various medical and regulatory Sponsor personnel to ensure the health and welfare of study participants.

Essential Duties and Responsibilities:

- Responsible for protecting the rights, safety and welfare of study participants.
- Responsible for ensuring that the clinical trial is conducted according to the investigational plan and all applicable regulations.
- Provide medical and scientific feasibility of all new sponsor inquiries.
- Review and evaluate protocols and provide clinical and scientific support.
- Liaise with sponsor regarding study design and site capabilities.
- Interact with regulatory bodies as relevant to clinical operations.
- Attend study initiation meetings.
- Present protocols at IRB meetings, as required.
- Assist Clinical Operations and sales/marketing efforts with Sponsor visits.
- Perform pre-study physical examinations, review lab data, ECGs and other medical information to ensure volunteers are medically and mentally fit upon entering the study.
- Perform on-study and post-study physical examinations to ensure that the physical and mental well being of volunteers is undiminished at the end of the study.
- Inform IRB and Sponsor as appropriate of relevant events.
- Review and sign CRFs/eCRFs at the conclusion of the study.
- Delegate the above as appropriate.

- Act as Principle Investigator/Co-Investigator as assigned.
- Weekend and off-hours work as necessary.

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.
- M.D. or D.O.
- U.S. Board Certification/DEA license
- Active license to practice medicine in the state of Wisconsin, or an active license that is transferable to Wisconsin within 3 months.
- 3-5 years M.D. experience
- Experience in conducting clinical research
- Strong interpersonal and leadership skills, self-motivation, and high personal integrity and ethics required.

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:

- Specialty in Internal Medicine, Emergency Medicine, or Family Medicine
- Clinical research experience within a CRO or Phase I research facility
- Experience conducting Phase I clinical trials

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