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## Junior 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.

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Original Date: 04 Aug 2014

Revision Date:

Position Reports To: Director of Clinical Operations

Position Supervises: None

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### Job Summary:

As Junior Investigator at Spaulding's Clinical site, you will be responsible for the conduct of clinical studies according to study protocols, review of safety data, and monitoring the safety of study participants enrolled into clinical trial protocols, as delegated by, and under the direction of, the Principal Investigator.

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### Essential Duties and Responsibilities:

#### Pre Study

- Oversee the informed consent process of study subjects.
- Perform screening examinations
- Review subject screening data, including subject medical histories, ECGs, radiographic studies, laboratory studies, and any other ancillary tests required per study protocol.
- Interact with client in-person (on-site) or via written, electronic or telephone correspondence to address any screening related questions.
- Screening review - Review of subjects eligibility based upon protocol inclusion and exclusion criteria

#### During study

- Review, initial and date all safety related data in a timely manner to include laboratory studies, ECGs and all other safety data as dictated by the study protocol.
- Coordinate with nursing staff to ensure proper medical coverage for clinical studies

- As needed, assist with training of clinic associates on ECG procedures, manual vitals procedures and assessment skills related to reporting adverse events
- Safety monitoring - Monitor, review, and track adverse events and serious adverse events. Institute PI-ordered treatment as needed.

### Post-study

- Safety monitoring
- Perform end-of-study physical examinations and provide follow-up for any ongoing adverse events
- Assist P.I. in review of Case Report Forms
- Assist P.I. with on-site client review of case report form
- Responsible for adverse drug assessments, evaluations, and documentation under guidance of PI
- Act as 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.

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### Skills/Qualifications

- Ability to read, write, and interpret the English language.
  - Strong interpersonal and leadership skills, self-motivation, and high personal integrity and ethics required.
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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:

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- Potential for exposure to toxic or caustic chemicals
  - Potential for exposure to blood borne pathogens
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**Education and Experience:**

- Currently licensed in the state of Wisconsin as a Nurse Practitioner, Physician Assistant DO or MD
  - Training in Basic Life Support and Advanced Cardiac Life Support
  - Board certified or Board eligible in a primary care specialty
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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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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