



Job Title: Clinical Research Coordinator  
Location: San Diego, CA  
Department: CNS & Medical  
Job Status: Exempt, Full-time  
Job Code: 800  
Reports To: Site Manager

## **JOB SUMMARY**

The Clinical Research Coordinator collects, documents, and maintains clinical data while ensuring compliance with protocol and overall clinical objectives.

## **ESSENTIAL DUTIES AND RESPONSIBILITIES**

- Complete charting for each prospective research participants.
- Responsible for gathering necessary information from the research participants (i.e. HIPAA, Medical Chart Release Authorization, Questionnaires).
- Responsible for the Informed Consent Process per the SOPs.
- Responsible for maintaining data and information in the source documents.
- Responsible for reviewing inclusion and exclusion criteria for the PI.
- Responsible for ensuring all trial specific procedures are followed in the order set forth by the study protocol.
- Responsible for maintaining various site logs (i.e. Site visit logs, study subject enrollment logs, screening logs, drug accountability logs).
- Review subject's information in preparation for the investigator's review.
- Responsible for completing source documents and transcribing the data onto the Case Report Form (CRF).
- Responsible for organizing each trial specific visit per the protocol's guidelines.
- Ensure all study procedures are completed according to the study protocol.
- Ensure the safety reports are submitted to the Regulatory Department.
- Assist the Regulatory Department with maintaining accurate information in all regulatory binders.
- Assist in training other staff members on the study protocol (i.e. the lab technician or medical assistant on lab procedures or study specific requirements).
- Ensure the diagnostic specimens are packaged per IATA guidelines.
- Responsible for reporting SAEs to the investigator and ensuring that the completed SAE report has been submitted to the Regulatory Department.
- Assist in any additional tasks assigned by the site manager.

## **INTERACTION**

Under general supervision of the site manager, will be responsible to establish positive communication with a variety of individuals to enforce compliance with protocol guidelines and ensure patient safety. Interacts daily with the site manager, staff.

## **JOB DESCRIPTION FOR CLINICAL RESEARCH COORDINATOR, PAGE 2**

research nurses, medical assistances, laboratory technicians, independent contractors (i.e. physicians), CRAs, Sponsors, and investigators.

### **REQUIREMENTS**

To perform this job successfully an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Minimum of a science background and 2-3 years of research experience.
- Prefer CCRC or CCRP.
- Working understanding of ICH, GCP and FDA regulatory requirements.
- Excellent verbal, written and organizational skills.
- Strong team player, and have the ability to multi-task.
- Must be detailed oriented.

### **PHYSICAL DEMANDS**

The physical demands of the job are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with qualified disabilities to perform the essential functions.

- Ability to travel locally and nationally.
- The ability to sit for several hours at a time.
- Communicate in person and by a telephone.
- Limited walking required.
- Limited to lifting up to 20 pounds.

### **WORK ENVIRONMENT**

The work environment is representative of those that an employee encounters while performing the essential function of this job. Reasonable accommodations may be made to enable individuals with qualified disabilities to perform the essential functions.

The work environment is indoors in a comfortable temperature controlled office environment. The noise level is quiet or minimal. The environment is typically free from dust and some hazardous materials will be present.