JOB DESCRIPTION – CLINICAL RESEARCH COORDINATOR

Job Title: Clinical Research Coordinator

Date: Monday, March 12, 2018

Classification: Non-Exempt

Salary grade/ range: DOE

Reports to: Clinical Research Coordinator

Position type: Full Time

Work Schedule: Monday- Thursday 8:30 am -5:00 pm; Friday 8:30 am – 3:00 pm

Position Description: Under the supervision of the Site Manager, the Clinical Research Coordinator is responsible for coordinating the approval processes and conduct of research protocols, such that the integrity and quality of the clinical research is maintained and the research is conducted in accordance with Good Clinical Practice Guidelines, federal and sponsor regulations and guidelines, Artemis Policy and Procedures and research protocols. The Clinical Research Coordinator manages screening, consenting, enrollment, randomization and study conduct from planning through study closeout. The Clinical Research Coordinator is required to perform and implement processes to assure study-related procedures are conducted as required and objectives and timelines are met. This role is also required to maintain accurate and timely documentation and communication with Investigators, participants, IRB, sponsors and other research related entities.

Skills/Competencies:

- Working knowledge and adherence to the policies, procedures, and regulations governing clinical research
- Awareness of the Federal regulations and guidelines governing the protection of human subjects (e.g., FDA, GCP/ICH guidelines, and HIPAA regulations) including California Bill of Rights
- Demonstrate capability to understand and follow a clinical study protocol, obtain training and seek assistance when needed, and accurately perform or assess required protocol procedures
- Demonstrate effective and professional communication (verbal and written) and ability to work efficiently with a diverse team of professionals
- Demonstrate excellent organizational and analytical skills, as well as attention to detail
- Demonstrate an ability to prioritize and triage multiple priorities effectively
- Proficient with Microsoft Office Software (Outlook, Word and Excel), Clinical Trial Management Systems (CTMS), Electronic Data Capture (EDC) systems, Interactive Voice Response Systems (IVRS/IWRS), and ediaries
- Demonstrate ability to collect vitals, perform EKGs, perform phlebotomy and process samples
Key Responsibilities:

- With assistance, prepare and process new study submissions to the IRB, protocol amendments, continuing review applications, protocol deviation reports, and Serious Adverse Event (SAE) reports according to Artemis and applicable IRB and sponsor policies and procedures
- Prepare and attend Investigator Meetings and post meeting educate and inform Investigators, supervisor, co-workers and other departments as appropriate, of all pertinent information required to execute the trial successfully
- Review source templates to ensure consistency with protocol and schedule of assessments; identify and communicate discrepancies to the Regulatory Specialist in a timely manner
- Work collaboratively with study participants, other staff and departments to complete research protocols, including performing study procedures, arranging necessary schedules and procedures, completing required subject related information in the CTMS, conducting visits and laboratory procedures, tracking investigational product and other protocol specific investigational procedures
- Conduct an initial review of patient medical records upon receipt; flag any diagnoses or medications that are different than currently recorded in the subject study chart and raise to the Investigator for review and assessment; update subject study chart and EDC based on feedback provided by Investigator
- Prepare and maintain all required documents and make them available internally and for regulatory authorities and/or the sponsor prior to, during and after the conduct of a clinical trial
- Prepare and participate in periodic site visits from sponsor, clinical research organizations (CROs), and regulatory authorities in the review of study specific regulatory documents, source documentation, case report forms and other associated study information
- Ensure required equipment and supplies are available to fulfill study requirements
- Participate in the determination of eligible candidates for study participation (includes awareness of other enrolling studies to assist in identifying potential candidates)
- Record data from source documentation and/or subject interaction onto electronic case report forms with awareness and attention to the requirements for accuracy, completeness and timeliness
- Attend to query resolution in a timely manner
- Assure research information is collected and stored in a manner that is compliant with regulations/policies and good clinical practice
- Perform packaging and shipping of study specimens (blood, urine, etc.) to the sponsor or laboratory in accordance with sponsor and shipping guidelines/regulations, maintaining appropriate documentation
- Ensure completeness and continuity of all study data by performing ongoing quality checks of clinical data that has been entered in source documentation and the electronic case report forms and any associated reports; this also includes the regular QC of Study Regulatory Binders with emphasis on the Delegation of Authority Log and associated training documentation
- Assist with archiving of study files at study closeout
- With supervision, take appropriate action to maintain clinical trial billing compliance
- Participate collaboratively in team meetings
- Maintain open and positive communication with Investigators, study participants, co-workers, other departments and sponsors
• Assist Investigator with the assessment and evaluation of potential subject pertinent medical and historical information to ensure only appropriate subjects are enrolled and remain eligible for continued participation; this includes providing a concise overview to the Investigator prior to the Investigator’s examination and assessment of the subject at each visit
• Participate in the ongoing informed consent process, ensuring that subjects, their families, and/or caregivers clearly understand what is expected of and from while participating in a clinical trial
• Participate in the training and instruction of others as to proper conduct of research related procedures as they are described in the protocol, deviating from the protocol only when a subject’s safety is at risk; and in a timely manner report all deviations from the protocol to the Principal Investigator and/or senior management who will help determine what additional reporting (i.e., Sponsor, CRO, IRB, etc.) is required
• Conduct routine QC for activities assigned to Research Assistants, including but not limited to collection of Vitals, EKGs, phlebotomy including processing and shipping, filing, chart prep, EDC entry and scheduling of vendor appointments
• Demonstrate initiative for continuous learning by identifying and participating in training, education and development activities to improve own knowledge and performance to sustain and enhance professional development
• Participate in and maintain certifications, licensure and credentialing as required by Artemis

Work Environment: Work is generally performed within an office environment with standard office and medical equipment.

Physical Demands: Sit – The person in this position will be sitting for most of the work schedule. Walk – the person in this position needs to occasionally move about inside the office to access file cabinets, office machinery or walk within office premises. Carry weight, push – Occasionally, this position might need to carry or push equipment weighting up to 50 pounds.

Travel: 15%

Required education and experience:

• Minimum education: High school diploma; Associates Degree or equivalent preferred
• Minimum one year experience in clinical research as Research Assistant, Clinical Research Coordinator, or similar position; combination of education and experience will be considered
• Bachelor’s degree in a related field is a plus
• Nursing License, Medical Assistant Certificate or similar certification is preferred

Additional eligibility qualifications: N/A

Other duties: Additional tasks may be assigned by supervisor