Clinical Research Coordinator:

PURPOSE
Perform a variety of clinical procedures to collect, record, report and interpret data on patients enrolled and/or seeking enrollment in clinical studies according to the protocol, standard operating procedures (SOPs), and Good Clinical Practice (GCP). Assist with daily workload planning.

RESPONSIBILITIES
• Provide clinical research support to investigators to prepare for and execute assigned research studies, including:
• Review study protocols, Case Report Forms (CRFs), other study-specific documents, and electronic data capture systems used to record clinical research data;
• Attend all relevant study meetings;
• Collect and submit regulatory/ethics documentation as required by the FDA and other regulatory bodies governing the conduct of clinical research;
• Recruit and screen patients for clinical trials and maintain subject screening logs;
• Orient research subjects to the study, including the purpose of the study, procedures, and protocol issues such as timelines for visits;
• Design and maintain source documentation based on protocol requirements;
• Schedule and execute study visits and perform study procedures;
• Collect, record and maintain research subject study data according to study protocol and SOPs, preserving quality control for content, accuracy and completeness;
• Handle lab testing and analysis, including preparation of specimen collection tubes and lab logistics;
• Monitor subject safety and report adverse reactions to appropriate medical personnel;
• Correspond with research subjects and troubleshoot study-related questions or issues;
• Participate in “huddles” to confirm daily study tasks are assigned to team members and are executed to the expected standards;
• Assist with study data quality checking and query resolution.
• Perform a variety of complex clinical research procedures including but not limited to ECG, sample collection, spirometry, vital signs, dose verification, cannulation and cardiac telemetry monitoring.
• Record, report and interpret study findings appropriately to develop a study-specific database.
• Assist investigator in verifying that research study objectives are met on time, within budget and according to applicable protocol requirements, clinical research regulations and quality standards.
• Provide training to new investigator site staff members on study-specific topics and requirements. Assist in maintaining adherence to investigator site staff training requirements by auditing and maintaining training records.
• Prepare for and attend study monitoring visits, study audits, and regulatory inspections with clinical research regulatory agencies.
• Assist research site with coverage planning related to staffing and scheduling for research projects.

• In-depth knowledge of departmental, protocol and study-specific operating procedures, consent forms, and study schedules
• Skill in carrying out required clinical procedures such as intravenous catheter insertion and spirometry testing
• Good skill in using MS Windows and Office applications such as Access, Outlook and Word
• Excellent interpersonal skills
• Ability to pay close attention to detail
• Ability to establish and maintain effective working relationships with coworkers, managers and clients

MINIMUM REQUIRED EDUCATION AND EXPERIENCE
• Bachelor's degree or educational equivalent; or High school diploma and 3 years' relevant work experience in a clinical environment or medical setting, e.g., medical assistant, assistant nurse, laboratory technician; or equivalent combination of education, training and experience
• Applicable certifications and licenses as required by company, country, state, and/or other regulatory bodies

PHYSICAL REQUIREMENTS
• Use of telephone and face-to-face communication requiring accurate perception of speech
• Use of keyboard requiring repetitive motion of fingers
• Frequent mobilization around the facility
• Occasional lifting and moving objects weighing up to 10 lbs/4.5 kg

EEO Minorities/Females/Protected Veterans/Disabled