Position Title: Clinical Study Coordinator

Position Summary: Responsible for the planning, implementation and overall direction of clinical research studies conducted on behalf of sponsors at the Frontage Clinical Research Center. The Clinical Research Coordinator is required to perform study procedures (dose, blood draw, perform vital sign, process blood samples, perform safety assessment under physician's guidance; to generate, evaluate, review and record study data on the source documents, to transcribe source data to case report forms (CRFs), to liaise with sponsor personnel, to maintain a high level of professional expertise through familiarity with the study protocol, investigator's brochure, and related study materials, and to participate in project team meetings. The Clinical Research Coordinator assists the Principal Investigator in conducting clinical research studies in compliance with applicable regulations and Good Clinical Practice (GCP) guidelines.

Responsibilities:

- Assists in the administration of informed consent to research subjects under the supervision of the Principal Investigator.
- Maintains a regulatory study file notebook or binder for a study protocol.
- Assists in the screening of research subjects to evaluate their eligibility for a clinical study.
- Develops a high level of familiarity and knowledge of the study protocol and flow chart of study procedures. Develops a strategy for implementing study procedures in compliance with the study protocol.
- Performs study procedures (e.g., start intravenous lines, venipunctures, obtain biological specimen samples, obtain ECG recordings, vital signs, safety assessments, etc.) as required by study protocol.
- Establishes and maintains source documentation for study protocols in conjunction with the Principal Investigator and Sub-Investigators.
- Records study data in the source documents. Evaluates and reviews study data to ensure accuracy and completeness.
- Transcribes study data from source documents to sponsor designated case report forms or records data for remote data entry if applicable.
- Resolves data queries in conjunction with the sponsor.
- Assists Principal Investigator with gathering and recording relevant data for adverse event reporting and expedited reporting of serious adverse events to the sponsor.
- Interacts with sponsor and Frontage senior management on subject recruitment activities and assists Frontage senior management with developing and tracking study budgets.
- Works on complex problems where analysis of situations or data requires an evaluation of numerous variables.

Requirements:

- Minimum of 3 years of hospital inpatient department work experience, preferred ER or ICU experience.
- Minimum of 1 year in clinical research conduct.
- Knowledge of FDA Regulations on clinical trial on human subjects and GCP guidelines.
- Good communication skills with the ability to interact with physicians, medical assistants, project managers, and sponsor personnel.

Qualified candidates should forward their resume to HumanResource@frontagelab.com. Please reference the job title in the subject line.