Job Description

POSITION: Clinical Research Coordinator

LOCATION: Winnipeg, CA

DEPARTMENT: Personal Health Care (PHC)

FLSA (US ONLY): Exempt / Non Exempt (Part-Time / Non- Salaried)

RESPONSIBLE TO

Associate Director, Clinical Operations

POSITION SUMMARY

The primary responsibility of the Clinical Research Coordinator is to conduct clinical studies according to FDA or Health Canada regulations and ICH/GCP Guidelines. The Clinical Research Coordinator performs all activities involved in conducting a clinical trial completely, accurately, and assumes a role in the promotion of clinical research.

GENERAL RESPONSIBILTIES

- Conducts clinical procedures
- Assist investigators with patient screening, enrollment, interim visits and final visits.
- Obtains IRB approved informed consent (ICF) , medical histories, and demographic information from potential volunteers
- Performs necessary procedures required per protocol to accomplish the screening visit such as but not limited to, Vital Signs, skin evaluations, BMI, height/weight and urine pregnancy testing.
- Answers questions, reviews protocol, and works closely with the screening coordinator, recruitment and regulatory department.
- Conducts subject interviews and schedules subject appointments
- Assesses subjects' protocol and medication compliance and documents adverse events including follow-up with subjects
- Ensures that the screening logs are up to date and notifies recruitment and management of the progress of the study.
- Completes all study related activities following the sites SOPs, policies, and protocol in order to meet the study timelines
- Prepares the subjects charts and on study source documents to be used per protocol during the conduct of the study
- Ensures that the documents created are verified by the QC department and obtains approval prior to use.

- Maintains professional and technical knowledge by attending educational workshops
- Protects sponsor confidentiality by limiting discussion of ongoing protocols with monitors and other industry representative
- Trains new employees and ensure their proficiency in activities and computer usage
- Conducts pre-study and kick-off meetings prior to the beginning of each study.
- Ensures that subject's payment is accurate and performed in a timely manner.
- Ensures that meals and proper study supplies have been ordered prior to the start of the study.
- Ensures that all data corrections have been made after study completion and before that study is paginated.
- Successfully manages the IRB/IEC/REB submission process per CR Global Policies and Procedures
- Works with Quality Assurance Auditors and Quality Control Team to ensure that quality standards are met during the startup, implementation and close out of all studies
- Reviews study reports and assists in the writing of reports, as required
- Communicates regularly with the client during the startup, implementation, and close of out studies assigned
- Execute other duties that may be required by other members of the management team as training and experience allows

SUPERVISORYRESPONSIBILITIES

Has no direct supervisory responsibility. Has dotted line supervisory responsibility over Clinical Research Assistants (CRAs) per assigned study.

WORKING CONDITIONSAND ENVIRONMENT

The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodations may be necessary and can be made, to enable individuals with disabilities to perform the essential functions.

The noise level in the work environment is usually moderate and dealing with groups of people is needed in this role. Primarily office setting. Work hours may vary according to the needs of the clinic and specific studies. Evening, weekend or holiday hours may be required.

QUALIFICATIONS&EDUCATION

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.

Qualifications:

Minimum thee (3) year Bachelor's Degree and 1 year of clinical research experience. To perform this job successfully, an individual must be able to perform each essential duty satisfactorily.

Skills and Abilities:

- Knowledge of issues in and principles of clinical research, including theory and practice.
- Knowledge of organizational policies, regulations and procedures.
- Skill in exercising a high degree of initiative, judgment, discretion and decision-making to achieve departmental and organizational objectives.
- Skill in preparing and maintaining records, writing reports and responding to correspondence.
- Ability to use computer programs such as Microsoft Outlook, Word, Excel, and Power Point.
- Ability to communicate effectively in verbal or written form.
- Ability to balance multiple priorities and handle confidential issues.
- Ability to identify and solve problems effectively and efficiently.
- Ability to communicate with patients, trial representatives, etc.
- Ability to react calmly and effectively in emergency situations.
- Ability to maintain a high level of organization, efficiency and accuracy
- Ability to work independently or as a contributing team member
- Ability to manage multiple priorities and flexible schedule.

The resumes can be submitted to sneufeld@cliantha.com, kstowe@cliantha.com