Job Description

POSITION: Clinical Research Manager

LOCATION: Winnipeg, CA

DEPARTMENT: Personal Health Care (PHC)

FLSA (US ONLY): Exempt

RESPONSIBLE TO

Associate Director Clinical Operations

POSITION SUMMARY

The primary responsibility of the Clinical Research Manager is to coordinate and supervise the conduct of multiple studies in accordance with the study budget while maintaining the highest standards of quality and customer satisfaction.

GENERAL RESPONSIBILTIES

- Manages client/Cliantha study communication of assigned studies by keeping key constituents informed: Investigator, Assistant Site Manager, Associate Director Clinical Operations, and clients. Listens and understands client needs and expectations and carefully manages the meeting of those needs with the help of the Assistant Site Manager or Associate Director Clinical Operations and others.
- Successfully manages multiple studies and the team performing those studies.
- Supervises and ensure the quality of each study managed in accordance with the study contract, study protocol, protocol amendments, Cliantha quality standards and other regulatory requirements, including the following:
    - Assists Business Development in the creation of proposals for customers, upon request
    - Assists and/or creates protocols according to CR guidelines
    - Creates and submits study budgets to Associate Director Clinical Operations, as requested
    - Manages individual study budgets to increase efficiency while minimizing financial and quality risks and assuring customer satisfaction and regulatory compliance
    - Creates and executes study plans and schedules
    - Determines and allocates internal and external resources, supplies and equipment

needed to meet study requirements
    - Ensures that all studies have a pre-study meeting, conducted per CR SOP by the Study Coordinator and attended by the Study Manager
    - Successfully manages the IRB/IEC/REB submission process per CR Global Policies and Procedures
    - Works with Quality Assurance Auditors and Quality Control Supervisor to ensure that quality standards are met during the start up, implementation and close out of all studies
    - Reviews study reports and assists in the writing of reports, as required

- Responsible for ensuring a safe work environment for study participants and staff
- Successfully creates and implements formal presentations and training materials as assigned
    - Ensures appropriate training and development of new and existing staff, documents training and maintains training binders as appropriate
    - Has an active role in each study to demonstrate the local management presence
- May serve on studies in other technical roles. In the event the Study Coordinator is absent, the Clinical Research Manager will fill their role
- Adheres to all company standard operating procedures and policies, regulatory requirements, national and regional laws as relating to subject recruitment and Cliantha Research
    - Demonstrated knowledge of Company's SOPs/policies and reviews policies at regular time intervals as directed.
    - Demonstrated knowledge of regulatory requirements, privacy and confidentiality laws, and GCP/ICH standards
    - Completes timesheets accurately and punctually

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 all essential duties 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:

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. Four (4) year degree required with two (2) years relevant experience. Experience in budgeting, resource allocation, technical writing, client/sponsor contact, and supervision preferred.

Skills and Abilities:

- Ability to analyze study protocols and estimates the time and labor required to execute a study
- Demonstrated knowledge of Company's SOPs/policies, regulatory requirements and quality standards (e.g. GCP, ICH GCP)
- Ability to anticipate and allocate required resources
- Ability to efficiently assign and supervise study related tasks
- Ability to effectively create and manage study budgets
- Ability to perform mathematical computations
- Expertise in standard computer software applications
- Excellent written and oral communication skills
- Ability to effectively interact with clients/sponsors
- Scientific knowledge and understanding of the mechanics, theory, and applicable regulations used in study conduct
- Ability to effectively communicate technical and scientific procedures and practices
- Ability to follow and interpret both oral and written instructions, including protocols
- Ability to effectively write proposals, protocols and study reports
- Knowledge of relevant scientific/medical terminology
- Excellent leadership qualities and team building skills
- Ability to train personnel in conduct of study procedures
- Ability to work with others in a positive and cooperative manner
- Ability to achieve goals

SUPERVISORY RESPONSIBILITIES

Has no direct supervisory responsibility. Dotted line to Clinical Research Coordinators and Clinical Research Assistance per assigned study.

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