

Prairie Education and Research Cooperative
Position Description

POSITION TITLE: Clinical Research Associate (Clinical Trial Monitor or CRA)

REPORTS TO: PERC Director/Chief Operating Officer
PERC Clinical Trial Manager

APPROVED BY:

President of the Board: _____ Date: _____

Director/Chief Operating Officer: _____ Date: _____

POSITION PURPOSE:

The Clinical Research Associate monitors activities at clinical study sites to assure adherence to Good Clinical Practices (GCPs), Standard Operating Procedures (SOPs), and study protocols. The incumbent is responsible to manage the collection regulatory documents, source document verification, and other field related tasks of multi-center research projects. Responsible for multiple projects and must work both independently and in a team environment.

ORGANIZATIONAL RELATIONSHIP

This position is under the direct administration of assigned Senior Clinical Research Associates (Sr. CRA's) and Clinical Trial Manager (CTM). It is anticipated that the employee will require daily direct supervision. The Director/COO will review performance on a regular basis. The employee may receive written and/or oral directives.

MAJOR TASKS, DUTIES AND RESPONSIBILITIES:

General Expectations

1. Sound knowledge of medical terminology and ability to learn clinical monitoring process
2. Ability to perform regionalized travel an average of 65%, depending on project needs.
3. Good verbal and written communications skills
4. Effective interpersonal and organizational skills and attention to detail
5. Computer literacy, proficiency in MS Office
6. Participates in continuing education and provides documentation of ongoing education in related field.
7. Must be willing and able to incorporate PERC customer service protocols as they relate to interactions with patients, families, physicians and co-workers.

Clinical Study Design

1. Collects and maintains study start-up documents including 1572s, CVs, signed CDA, investigator study files, enrollment logs, etc.
2. Participates in preparation of Investigator Meetings materials
3. Perform site monitoring duties and follow-up to ensure identified deficiencies are corrected; travel as required to accomplish responsibilities.
4. Assist in assessing the suitability of potential investigative sites through telephone screening interviews, regulatory document review and disseminating clinical trial information; conduct site qualification visits to determine adequacy of facilities and staff, patient recruitment and retention potential, ability to comply with regulatory requirements, and overall interest and commitment of principal investigator to conduct and complete the planned clinical study.

Clinical Study Execution

1. Assists in providing clinical-related progress of project schedule to CTM and/or CST
2. Develops ability to independently conduct pre-study, initiation, monitoring and closeout visits
3. Maintains positive and cooperative relationship in day-to-day interactions and communications with investigators and study sites
4. Reviews Case Report Forms (CRFs) and ensures they are filled out properly, completely, accurately and consistently. Provides feedback to the Clinical Study Team (CST) on issues pertaining to the completion of the CRFs
5. Ensures CST is adequately informed of protocol and study procedures
6. Collection and review of regulatory documents
7. Ensures clinical supplies are properly stored and accounted for, and any necessary blinding is maintained
8. Ensures on-site personnel understand and comply with the GCPs and PERC and/or Sponsor Standard Operating Procedures (SOPs)
9. Ensures site understands and complies with adverse event reporting requirements
10. Ensures patient safety is maintained and informed consent procedures are carried out properly
11. Reports Serious Adverse Events (SAEs) and reconciles on-site and in-house reports
12. Participates in data management processes including the collection of data, and the identification and resolution of data queries
13. Implements, tracks and reports patient recruitment and retention at investigational sites
14. Ensures lab certification, test equipment calibration, and pertinent normal laboratory values are maintained
15. Conducts Source Data Verification (SDV)
16. Maintains site monitoring visit schedule
17. Ensure IRB certification and documentation is current
18. Identifies study-related issues

Clinical Study Reporting

1. Completes the final reconciliation of clinical supply and assists study team in the final reconciliation of the adverse event database and retrieving any additional study file documents
2. Maintains administrative files at study site and PERC Master File
3. Completes site visit reports, site correspondence, telephone logs, and other relevant documents
4. Communicates with finance coordinator to ensure timely site and/or vendor payments

KNOWLEDGE AND SKILL REQUIREMENTS:

1. Demonstrated effectiveness working collaboratively in cross-functional teams
2. Possess previous computer experience.
3. Possess good organizational skills.
4. Is able to make objective judgments.
5. Possess good oral and written communication skills.

MINIMUM QUALIFICATIONS

Work requires graduation from an accredited degree program providing clinical training as a Registered Nurse (RN – with a current Illinois license), Physician’s Assistant (PA) or Pharmacist plus one year of healthcare experience; or one of the following equivalents:

- a. Completion of an allied health degree (e.g., Respiratory Therapy, Radiologic Technology, Licensed Practical Nurse) plus a minimum of three years healthcare experience; or
- b. Completion of a Bachelor’s degree in Public Health, Health Administration or a related area with no additional experience; or
- c. Completion of a bachelor's degree in scientific, math, or related field.

Must be Certified Clinical Research Professional Coordinator and/or Associate or working towards certification.

PREFERRED QUALIFICATIONS

1. 1 year experience in research related activity.
2. Knowledge of database concepts and formats.

WORK ENVIRONMENT:

1.) This position requires the following demands:

A.) Physical Demands

Must appear well groomed and professional.

Ability to travel average of 65% annually

This position is primarily office based. Home-based office work as project needs allow.

B.) Mental Demands

Must have the ability to maintain composure under stress using tact and good judgment.

Must work well under supervision as well as independently