

Prairie Education and Research Cooperative Position Description

POSITION TITLE: Senior Clinical Trial Manager

REPORTS TO: PERC Director/Chief Operating Officer
PERC Medical Director
PERC President of Board

APPROVED BY:

President of the Board: _____ Date: _____

Director/Chief Operating Officer: _____ Date: _____

POSITION PURPOSE:

Develop, coordinate, and implement research and administrative strategies essential to the successful management of phase II, III and IV clinical trials research projects conducted by Prairie Education and Research Cooperative's (PERC) Trial Management Organization Department; perform a variety of duties involved in the management, organization, documentation and compilation of clinical research data; function in manager/preceptor capacity for Clinical Trials Research Team.

MAJOR TASKS, DUTIES AND RESPONSIBILITIES:

- 1.) Integrates PERC's mission and vision in the daily tasks through dedication to quality improvement and collaborative working relationships.
- 2.) Full commitment to Quality Assurance, Medicare Compliance, and the Health information Portability and Accountability Act (HIPAA) as defined by PERC policy and the Federal Government.
- 3.) Knowledge and compliance with all OSHA guidelines.
- 4.) Maintains strict confidentiality of sensitive material and information.
- 5.) Develop, coordinate, implement, and oversee research and administrative strategies essential to the successful management of phase II, III and/or IV clinical trials research projects conducted by PERC; perform a variety of duties involved in the management, organization, documentation and compilation of clinical research data for sponsor, participating sites and FDA; function in manager/preceptor capacity for Clinical Trials Research Team.
- 6.) Develop systems for the establishment and refinement of guidelines in the collection of clinical data and administration of clinical trials; design and evaluate alternative methodology as necessary.

- 7.) Advise and assist national principal investigator/sponsor and other team members in the development of plans, time lines, and processes for clinical research studies; coordinate the ongoing analysis and modification of protocols; recommend amendments to study protocols as appropriate.
- 8.) Assure site coordinators' and physicians' adherence to Federal Food and Drug Administration and protocol guidelines; identify potential problems and/or inconsistencies and take action as appropriate (e.g. Site PI, Sponsor, IRB and/or FDA notification).
- 9.) Coordinate and lead the work of the Clinical Research Team and provide feedback to PERC Administration on a routine basis; conduct cross-functional research team meetings at least two times monthly and ensure meeting minutes specific to each clinical trial(s) being managed is maintained.
- 10.) Advise and assist the PERC administration in initial contacts and development of relationships with outside partners and internal functional groups for potential projects including trial budget and contract negotiations.
- 11.) Assist in the development of protocols.
- 12.) Responsible for project specific standard operating procedures (e.g. monitoring plan), provide oversight in the development of informed consent templates, case report forms (CRF) and instructions, site selection materials, procedure/in service manuals, project newsletter, and other monitoring tools for the clinical trial.
- 13.) Oversight in assessing the suitability of potential investigative sites through telephone screening interviews, regulatory document review and disseminating clinical trial information; conduct/oversee 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. Communicate site qualification issues with Sponsor as needed.
- 14.) Plan and implement trial-specific Investigator/Coordinator meetings.
- 15.) Assist Sponsor with DSMB member selection, obtain consulting agreements, provide oversight in the scheduling and implementation of regular DSMB conference calls/face-to-face meetings as per trial needs.
- 16.) Assure that the research site personnel, including the investigators, are conducting the study according to GCP guidelines; oversee site monitoring visits and sign off on all site visit reports as needed.
- 17.) Assist in the creation and delivery of presentations that convey the result of clinical research projects/data to healthcare professionals at major national and international conferences. Assure that presentations are legible and that data are presented in a professional and understandable way.
- 18.) Maintains pertinent orientation and SOP manuals and trial-specific training documentation for PERC study team. Assures the Manual of Operating Procedures Manual for each clinical trial is being updated as needed.
- 19.) Provide oversight with the design and implementation of Action Plans to identify and initiate clinical centers responsible for patient enrollment.
- 20.) Monitors progress of ongoing trials on a weekly basis. Works with Clinical Trials Research Team to Interpret weekly statistics on patient enrollment, case report

- form submissions, delinquency reports, and edit reports and assists team in the development of Action Plans to address problem centers as needed.
- 21.) Participates in all conference calls and all study-related meetings. Ensures and agenda and all supportive documentation is available to persons participating in the call/meeting. Ensures minutes are circulated to all attendees as needed.
 - 22.) Assist with the design and implementation of PERC quality assurance program to include regularly scheduled audits of Multicenter research files for thoroughness, accuracy and completeness. Discuss findings with Clinical Trials Research Team and QA Manager and implement Corrective Action as needed.
 - 23.) Performs other tasks and responsibilities as directed by the Director/COO and/or Medical Director.

KNOWLEDGE AND SKILL REQUIREMENTS:

- 1.) 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 two years healthcare experience and five years clinical trial experience; or
 - b. Completion of a master's degree in Public Health, Health Administration with three years directly related clinical trials research experience; or
 - c. Completion of a bachelor's degree plus a minimum of five years directly related experience in clinical trials research; or
 - d. Completion of a bachelor's degree plus a minimum of six years closely related research experience.
- 2.) Possess a positive and diplomatic personality with the ability to function independently as well as in a team member role.
- 3.) Possess keen attention to detail.
- 4.) Possess previous computer experience.
- 5.) Possess good organizational skills.
- 6.) Is able to work under stress (sometimes emergent) and accept constructive criticism.
- 7.) Is able to make objective judgments.
- 8.) Possess strong oral and written communication skills, as well as critical decision-making skills.
- 9.) Must have at least three years experience in cardiology.
- 10.) Must be Certified Clinical Research Professional Coordinator

WORK ENVIRONMENT:

- 1.) Each job requires the following demands:
 - A.) Physical Demands
 1. Must possess good physical and mental health.
 2. Must be capable of stooping, bending, stretching and lifting.

3. Must be able to stand and walk for long periods.
4. Must appear well groomed and poised at all times.
5. Must possess manual dexterity to handle and manipulate equipment and appliances.

B.) Mental Demands

1. Must have the ability to control emotions and maintain composure under stress using tact and good judgment.
2. Must be able to adjust to various personalities and situations.

C.) Special Demands

1. Must be self-confident and maintain a positive attitude.
2. Must be capable of performing in an environment that demands extreme consciousness, emotional stability, attention to the minute details and keen observation.
3. Must have patience and tact in dealing with sponsors, contractors, doctors, co-workers, and other departments.
4. Must have ability to work effectively in an environment which tends to be tension provoking.
5. Must be able to communicate effectively with sponsors, contractors, doctors, co-workers, and other departments.
6. Must work well under supervision, as well as independently and be able to take constructive criticism.