

Prairie Education and Research Cooperative Position Description

POSITION TITLE: 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 principal investigator(s) at Prairie Education and Research Cooperative (PERC); perform a variety of duties involved in the organization, documentation and compilation of clinical research data; function in 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, and implement research and administrative strategies essential to the successful management of phase II, III and/or IV clinical trials research projects conducted by principal investigator(s) at PERC; perform a variety of duties involved in the organization, documentation and compilation of clinical research data; function in 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 principal investigator 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.) Confer with site coordinators and physicians to explain protocol and to elicit compliance with regulations; assure adherence to Federal Drug Administration and protocol guidelines; identify potential problems and/or inconsistencies and take action as appropriate.
 - 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 as needed.
 - 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 the development of informed consent forms, case report forms (CRF) and instructions, site selection materials, procedure/in service manuals, project newsletter, project specific standard operating procedures, 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 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.
 - 14.) Assurance that the research site personnel, including the investigators, are conducting the study according to GCP guidelines.
 - 15.) Assurance that all applicable regulatory requirements are being met by the investigator's site.
 - 16.) 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.
 - 17.) Maintains pertinent orientation and SOP manuals.
 - 18.) Assist with the design and implementation of PERC quality assurance program to include regularly scheduled audits of research records for thoroughness, accuracy and timely submission to sponsoring company.

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 and/or Assistant or working towards certification.

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 patients and the public.
4. Must have ability to work effectively in an environment which tends to be tension provoking.
5. Must be able to communicate effectively with patients, doctors, co-workers, and other departments.
6. Must work well under supervision, as well as independently and be able to take constructive criticism.