

## **Prairie Education and Research Cooperative Position Description**

POSITION TITLE: Project 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:

Assist in the coordination and implementation of research and trial management 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 organization, documentation and compilation of clinical research data; report to Clinical Trial Manager and/or Senior Clinical Trial Manager as appropriate to job duties and responsibilities.

### 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.) Coordinate and implement research and trial management 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 organization, documentation and compilation of clinical research data for sponsor, participating sites and FDA; report to Clinical Trial Manager and/or Senior Clinical Trial Manager as appropriate to job duties and responsibilities.
- 6.) Advise and assist PERC multi-center team in the development of plans, time lines, and processes for clinical research studies; recommend amendments to study protocols as appropriate.

- 7.) Confer with site coordinators and physicians to explain protocol and to elicit compliance with regulations; assist Sr. CTM/CTM the conduct of site selection/site initiation visits and ongoing site training; assure adherence to Federal Food and Drug Administration and protocol guidelines; identify potential problems and/or inconsistencies and take action as appropriate (e.g. Senior Clinical Trial Manager, Site PI, Sponsor, IRB).
- 8.) Participate in cross-functional research team meetings at least two times monthly and maintain meeting minutes specific to the clinical trial(s) being managed.
- 9.) Assist 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.
- 10.) Assist with assessing the suitability of potential investigative sites through telephone screening interviews, regulatory document review and disseminating clinical trial information; conduct/assist Clinical Trial Manager with 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 Sr. CTM/CTM as needed.
- 11.) Assist in the implementation of trial-specific Investigator/Coordinator meetings.
- 12.) Assist with regularly scheduled DSMB conference calls/face-to-face meetings as per trial needs and assist with the maintenance of all DSMB materials (e.g. minutes, charter, etc.).
- 13.) Assurance that the research site personnel, including the investigators, are conducting the study according to GCP guidelines; oversee site monitoring visits and sign off on site visit reports as needed.
- 14.) Assurance that all applicable regulatory requirements are being met by the investigator's site by maintaining Investigational Site Master File with all required regulatory documents.
- 15.) Assist, as needed, the Senior Clinical Trial Manager 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.
- 16.) Maintains trial-specific training documentation for PERC study team. Assists in designing and updating the Manual of Operating Procedures Manual for each clinical trial as needed.
- 17.) Assist with the design and implementation of Action Plans to identify and initiate clinical centers responsible for patient enrollment.
- 18.) Monitors progress of ongoing trials on a weekly basis. Interprets weekly statistics on patient enrollment, case report form submissions, delinquency reports, and edit reports. Reports to Senior Clinical Trial Manager and assists in development of Action Plans to address problem centers as needed.

- 19.) Participates in all conference calls and all study-related meetings. Prepares agenda and minutes. Ensures all supportive documentation is available to persons participating in the call/meeting.
- 20.) Assist with the implementation of PERC quality assurance program to include regularly scheduled audits of Multicenter research files for thoroughness, accuracy and completeness. Report findings to Senior Clinical Trial Manager and QA Manager as needed.
- 21.) Performs other tasks and responsibilities as directed by the Senior Clinical Trial Manager and/or Director/COO.

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 two years directly related clinical trials research experience; or
  - c. Completion of a bachelor's degree plus a minimum of three years directly related experience in clinical trials research; or
  - d. Completion of a bachelor's degree plus a minimum of four 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 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 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.