Position Description

DATE: December 2021

POSITION TITLE:	Protocol Monitor I	**CLASSIFICATION:**	Exempt
REPORTS TO:	Protocol Director or Director of Coordinating Center	**SUPERVISES:**	None

Summary:

Through monitoring of clinical sites, ensures that the research conducted, recorded, and reported to external authorities complies with the protocol, all procedural documentation, and Good Clinical Practice (GCP) guidelines. Must have detailed and current knowledge of JCHR standard operating procedures, GCP, Code of Federal Regulations, and local country regulatory requirements. For each study, must have in-depth knowledge of the study protocol and procedures, regulatory issues specific to the protocol, and the site monitoring plan. Works independently with limited direct supervision.

Duties and Responsibilities:

The core duties and responsibilities that follow will vary by project and by the individual selected to perform them. Below is a listing of the types of tasks associated with this position.

Core Monitoring Responsibilities:

- Monitor clinical trial study protocols; ensure investigator/site compliance with the protocol and study procedures.
  - Track certification process for sites.
  - Conduct remote monitoring according to the study's monitoring plan and JCHR's SOPs.
  - Review and record data queries and protocol deviations.
  - Track adverse event-related effects and device issues (when necessary).
- Allocate study supplies to sites (if required by the study).
- Maintain frequent contact with site staff to ensure the study is performed appropriately.
- Conduct in-depth performance reviews of study sites with the protocol's oversight committee.
- Facilitate monthly site discussions with JCHR staff members to review monitoring reports.
- Conduct site visits (if JCHR-certified), including site qualification; initiation; interim; for cause; and close-out monitoring visits.

- Write and distribute site visit reports within established time lines; track resolution of outstanding issues.

Other Responsibilities

Other responsibilities may or may not include the following:

- Assist in the development of protocol and informed consent documentation, as well as Case Report Forms, procedure manuals/guides, and test plan documentation for study websites (when required).
- Prepare and submit yearly JCHR Institutional Review Board (IRB) renewal application.
- Assist in the development of study supply budgets.
- Assist in the management of the Data Safety and Monitoring Board (if required by the study).
- Contact the applicable device/drug company to provide study updates.
- Communicate with sponsors to provide study reports.
- Submit reports to regulatory bodies (IRB and Food and Drug Administration [FDA]) when devices were used in a study.
- Deliver study group presentations regarding items of importance.

General Responsibilities and Comments:

- Participate in professional development activities.
- Attend training sessions on GCP and other defined protocol components.
- Work with JCHR staff members to continuously improve processes and resolve issues.
- Interpret and implement management policies and operating practices as they relate to complying with FDA matters of compliance in clinical research.
- Work performed affects JCHR operations to a substantial degree as any clinical study performed without meeting regulations could cause harm to the business and loss of business.
- Each study is a major assignment as this is the basis of the business.
- Considered an expert in their field and abides by GCP. Any errors in research findings must be reported immediately to management.
- Investigate and resolve issues with studies on behalf of management.
- Work independently under general supervision.

Skills, Knowledge, and Abilities May Include:

- Microsoft Office, Outlook.
- Detail attentiveness: exercises a careful and precise approach to task accomplishment. Conforms to strict tolerances and maintains accurate documentation.
- Communication: excels in relating well to others. Adept at negotiating and relationship building. Excellent oral and written communication skills.

- Flexibility: multitasks comfortably and handles competing deadlines and priorities simultaneously. Remains productive and focused despite a full workload. Effectively copes with accelerating changes.
- Independence and cooperation: self-starter who carries out assignments without direction. Continuously finds new and better ways to perform tasks. Can also work as part of a complex team environment.
- Organization: develops effective strategies to attain good performance. Makes accurate assessment of needs.
- Planning: develops effective strategies to attain good performance. Anticipates and resolves conflicts.
- Versatility: performs a broad range of assignments with efficiency and accuracy.
- Time management: uses systematic methods to accomplish more in less time. Sets realistic time goals.
- Problem-solving/decision making: effectively resolves issues at early stages. Can examine problems from multiple angles and develop practical, logical solutions. Uses discretion to make important decisions involved in protocol monitoring.
- Understands and implements the precepts of GCP.
- Performs and properly executes the role of a protocol monitor to ensure a successful trial.
- Conducts travel in accordance with project needs and corporate travel policies.

Education and Experience:

- Education: Bachelor's Degree preferred, or equivalent training and experience.
- Experience: at least 1 year of experience in clinical research.
- Training in and demonstrated understanding of the regulatory obligations of the clinical site monitor.
- Association of Clinical Research Professionals Certified Clinical Research Associate or Society of Clinical Research Associates certification desirable.

Work Environment:

This job operates in a professional office environment. This role routinely uses standard office equipment such as computers, phones, copiers, filing cabinets, calculators, and fax machines.

Physical Demands:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job.

While performing the duties of this job, the employee is occasionally required to stand; walk; sit for long periods; use hands to finger, handle or feel objects, tools or controls; reach with hands and arms; climb stairs; balance; stoop, kneel, crouch, or crawl; talk or hear; and taste or smell. The employee must occasionally lift or move up to 25 pounds. Specific vision abilities required by the job include close vision; distance vision; color vision; peripheral vision; depth perception; and the ability to adjust focus.

Position Type/Expected Hours of Work:

This is a full-time position. Days and hours of work are Monday through Friday. This position occasionally requires long hours.

Other Duties:

Note: This job description is not designed to cover or contain a comprehensive listing of activities, duties, or responsibilities that are required of the employee for this job. Duties, responsibilities, and activities may change at any time with or without notice.