Position Description

DATE: June 2018

POSITION TITLE:	Protocol Manager I	**CLASSIFICATION:**	Exempt
REPORTS TO:	Director of Coordinating Center or Protocol Director	**SUPERVISES:**	May supervise Research Assistants and Protocol Monitors (depending on project)

Summary:

Provides general clinical trial management via oversight of trial conduct and the execution of a protocol (document that describes the objectives, design, methodology, statistical considerations, and organization of a trial) from study start-up to final closeout. Ensures that the clinical trial is conducted appropriately as per Food and Drug Administration regulations, Good Clinical Practice (GCP) guidelines, and JCHR Standard Operating Procedures.

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.

- Assist in the development of the protocol and Informed Consent Form per federal and local regulations.
- Develop Case Report Forms.
- Assist in study website development and testing.
- Create the following manuals:
  - Site procedures
  - Internal procedures
- Create the protocol review task list to ensure that remote- and risked-based monitoring guidelines are followed.
- Prepare the initial Institutional Review Board (IRB) submission as well as all renewals throughout the duration of the protocol.
- Collect, review, and submit site-central IRB documents.
  - For sites using local IRBs, submissions and approval letters are monitored remotely.
- Serve as primary contact with the central IRB to handle any regulatory or follow-up issues.

- Plan, schedule, and conduct periodic (i.e., weekly, monthly) study-related conference calls with investigators, coordinators, the Data Safety Monitoring Board, and the Operations Committee.
- Work with the Protocol Director and administrative staff to develop budgets with vendors such as the central lab, subject matter experts, and inventory suppliers.
  - Prepare Statements of Work for these vendors (as appropriate).
- Manage study inventory and supply shipments to sites.
- Train clinical study site personnel on procedures and the proper documentation of the protocol process.
- Mentor junior JCHR staff; train protocol monitors.
- Attend weekly meetings to discuss and review study-related activities such as monitoring reports and other pending documentation.
- Investigate and resolve any site issues related to the execution of the protocol or data entry.
- Address site technical issues and troubleshoot trial devices (as applicable).
- Document site protocol and procedural deviations.
  - Provide retraining, guidance, support, solutions, or recommendations (as applicable).
- Function as an integral part of budget development and preparation.
- Facilitate and negotiate contracts with external partners.
- Communicate with regulatory agencies for investigational studies.

Skills, Knowledge, and Abilities May Include:

- Ability to lead and manage junior staff.
- Excellent organizational skills.
- Knowledge of the Code of Federal Regulations, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, and GCP guidelines.
- Ability to identify and address issues and problems early.
- Works independently and also as part of a team.
- Ability to multitask, prioritize, and troubleshoot issues.

Education and Experience:

- Education required: Bachelor’s degree.
- Experience: 2+ years of clinical research experience.

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, with typical work hours from 8 a.m. to 5 p.m. 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.