Position Description

DATE: May 2018

POSITION TITLE:	Director of Coordinating Center	**CLASSIFICATION:**	Exempt
REPORTS TO:	Executive Director	**SUPERVISES:**	One (or more) Protocol Managers or Protocol Monitors

Summary:

Takes overall responsibility for securing funds for clinical trials. Designs and executes clinical trials.

Duties and Responsibilities:

- Act as a JCHR Principal Investigator on designated studies.
- Write and maintain ownership of grant applications, reports, and renewals.
- Write and maintain ownership of Investigational New Drug (IND), Investigational Device Exemption (IDE), and Institutional Review Board applications, reports, and renewals.
- Contribute to and review draft language of contracts with third-party collaborators.
- Create project-related budgets; approve project expenditures.
- Respond to high-level site protocol questions and issues that cannot be addressed by a Protocol Manager or Protocol Monitor.
- Complete protocol/Informed Consent Form development and documentation.
- Perform protocol monitoring:
  - Participate in the development of the protocol monitoring plan.
  - Conduct a limited number of clinical site qualification visits or on-site study monitoring visits.
- Recommend agendas for the study Operations Committee, Steering Committee, Data Safety and Monitoring Board, and other planning calls; provide leadership during calls.
- Contribute content for Standard Operating Procedures and Instruction Manuals; review and approve final versions.
- Participate in manuscript and abstract development as an author.
  - Draft and edit content; review proposed content as required.
- Provide external IND/IDE protocol review for partner funding bodies such as the Juvenile Diabetes Research Foundation.

- Complete the final review and sign-off of the following elements:
  - Project development and tasks
  - Financial disclosures
  - Food and Drug Administration IND/IDE submissions
  - Manuscript or meeting presentation submissions

Skills, Knowledge, and Abilities May Include:

- Strong interpersonal communication and writing skills.
- Task-delegation abilities.
- Team leadership skills.

Education and Experience:

- Master's degree or higher.
- Grant development or budget development-related experience.
- Experience designing and/or coordinating clinical trials.

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.