JOB TITLE: Clinical Operations Associate

Working under the direction of a Project Manager (or other senior staff), the COA will provide support and assistance to Trial Runners CRAs, PM, and other staff members in compliance with applicable FDA, ICH/GCP guidelines, global regulations, and Trial Runners Standard Operating Procedures.

RESPONSIBILITIES:

- Assist with the construction of various forms/templates including the informed consent template, CRF binders, template source documents, training manuals, regulatory binder, procedure manual, and any other materials as needed
- Coordinate and prepare minutes for project team meetings
- Assist with Trial Master File submissions and quality control
- Collaborate with teams to complete projects as necessary
- Perform project related tracking
- Perform data review
- Prepare Investigator Payments
- Enter information into the CTMS

REQUIREMENTS:

- Excellent written and verbal communication skills and detail-oriented skills
- Various computer skills – Excel, Word, PowerPoint, Microsoft Outlook
- Must be able to stand for long periods of time
- Frequently move 25 lbs. or more
- Frequently move about the office to access files, office machinery, etc.
- Frequently operate office machines – computers, copiers, printers, fax machine, etc.
- Frequently navigate stairs
- Participate in company required training programs

EDUCATION REQUIREMENTS:

- 4 year college degree preferred, but not required.

NOTE: This job description is not intended to be all inclusive. Employee may perform other related duties as delegated to meet the ongoing needs delegated of the company.