EMPLOYEE POSITION DESCRIPTION

Job Title: Senior Clinical Research Associate	**Department:** Clinical
☒ **Exempt**	☐ **Nonexempt**

Position Description:
The Senior Clinical Research Associate (Sr. CRA) assists with the planning and development of high-quality clinical activities to support Francis Medical projects. The Sr. CRA has clinical research experience and an understanding of research methodology, regulations, and guidelines. The Sr. CRA has experience assisting with the development of clinical strategies and/or plans, protocol development and execution, monitoring, and ensuring data quality and management of clinical studies. The Sr. CRA collaborates with CROs and other vendors in the execution of clinical trials and interacts with study investigators and other study staff members. The Sr. CRA will monitor clinical research sites in accordance with FDA Regulations, other global regulatory bodies, GCP and ISO compliance, and company SOPs.

Principal Responsibilities:
- Support clinical trials in collaboration with other clinical team members pertaining to site qualification, initiation, site management, data management and other ongoing tasks to support clinical trials.
- Perform site activities in compliance with GCP and FDA regulations for clinical trials.
- Assist with the development of study-related documents, including case report forms, study manuals, and other study-related tools.
- Assists with data management activities, query generation and resolution.
- Reviews informed consent forms and site activation documentation.
- Assists in planning and preparing materials for investigator and coordinator meetings.
- Assists with reporting study metrics, e.g., subject screening and enrollment, data collection, and documentation of adverse events.
- Assists with the preparation of study summary reports for presentations, publications and regulatory submissions.
- Provide input to the data management plan, monitoring plan, safety plan and other study-specific plans.
- Conducting pre-study, initiation, routine (as needed to ensure protocol compliance), and close-out site visits.
- Training study coordinators/investigators on protocol, including study procedures, CRF completion, enrollment, informed consent, and study product.
- Working with staff at study sites to resolve data discrepancies.
- Obtaining/reviewing/processing of regulatory and study-specific documents from investigative sites.
- Maintaining investigational product accountability.
- Monitoring IRB requirements.

Qualifications, Education & Experience:

Must Have:

- Bachelor's degree, preferably in a medical/scientific field.
- 4+ years' experience supporting clinical research or similar experience in a medical and/or scientific area.
- Master's degree will substitute for 1 year of experience.
- In-depth knowledge and proficiency in FDA regulations and ICH/GCP guidelines.
- Ability to anticipate and meet deadlines, prioritize work, strong attention to detail, and the ability to retain confidential information.
- Proficiency in MS Office, including PowerPoint, Excel and Word.
- Must be customer service oriented with strong interpersonal skills.
- Excellent organizational, written, and verbal communication skills.
- Effectively build and maintain positive relationships with physicians, peers, and colleagues across all organizational levels.
- Ability to multitask effectively while maintaining high-quality outputs.

Nice to Have:

- Proven experience working within an FDA IDE pre-market clinical study.
- Strong knowledge and understanding of prostate anatomy.

Working Conditions:

- Occasionally exerting up to 20lbs and lifting to 50lbs.
- Significant work pace and pressure due to deadlines of a start-up organization.
- Operate a computer and other office equipment, proficient in Microsoft Office software.
- Travel will be required 25-50% depending on the project life-cycle.
- Position based in Maple Grove, MN.

Competitive salary and benefits package.
To apply: Submit your resume to hr@francismedical.com