FHI CLINICAL
Mission-driven clinical research

Senior Clinical Research Associate

Summary of The Position: The Senior Clinical Research Associate (CRA) monitors activities at clinical study sites to assure adherence to Good Clinical Practices (GCPs), standard operating procedures (SOPs), study protocols and applicable regulatory requirements. Reviews study documents as required and prepares site visit reports. May be responsible for multiple projects and must work both independently and in a team environment. Participates in the study development and start-up process including reviewing protocols, designing and/or reviewing case report forms (CRF), preparing informed consent forms (ICFs), developing study documents, organizing and presenting at investigator meetings, working with management on a monitoring strategy and/or developing project-specific CRA training. May participate in clinical training programs and maintain awareness of developments in the field of clinical research as needed. May provide a benchmark of monitoring competence to inexperienced/less experienced colleagues. Prepares clinical documents, business correspondence and procedural manuals. Maintains systems and processes necessary to report trial status and activities and to help ensure that quality, regulatory-compliant clinical projects are conducted on time and within budget. Depending upon the level of experience, may become involved, when required, in other areas of study management and staff training and contribute to the review of sponsor/client's and/or FHI Clinical's systems and procedures as appropriate.

Essential Functions:

- Assists in the preparation of routine protocols, informed consent/assent forms, SOPs and other appropriate study documentation.
- Monitors clinical trials to ensure subject safety and compliance with the study protocol, applicable regulations and ICH/GCP guidelines; may be done with supervisor.
- Coordinates necessary activities required to set-up, monitor and close-out clinical trials sites.
- Conducts site evaluation/assessment, initiation, routine and close-out monitoring visits; may require minimum supervision.
- Completes accurate monitoring visit reports.
- Develops training materials and conducts training for study implementation based on company policies and SOPs.
- Contributes to the development of and implementation of protocols and informed consents/assents for research studies.
- Provides guidance on any protocol-related issues.
- Manages budget to ensure CRA activities are completed as per contract.

- Develops, reviews and maintains key study documents to ensure adequate resource and reference documentation.
- May serve as a liaison with internal and external partners to ensure effective collaboration efforts.
- Oversees planning of meetings, site visits and drafting necessary documents.
- Ensures compliance with applicable government regulations when writing and reviewing protocols, analysis plans, reports and manuscripts.
- Provides input on CRF development, analysis, study design and material management.
- Performs and coordinates all aspects of the clinical monitoring and site management process in accordance with ICH Good Clinical Practice, applicable regulations and FHI Clinical SOPs.
- Conducts site visits to assess protocol and regulatory compliance and manages required documentation.
- Updates and maintains study specific tracking tools.
- May function as project manager on assigned projects, taking on a lead role to achieve specific milestone goals to completion.
- Responsible for ensuring that data will pass international quality assurance audits.
- Represents FHI Clinical in the global clinical research community and develops and maintains collaborative relationships with investigational sites and clients

Knowledge, Skills and Abilities:

- Ability to review and approve the work and written reports of team members
- Proven clinical monitoring skills
- Ability to develop and prepare applicable study tools and documents
- Effective management skills of at least one staff member
- Project management capabilities including planning, tracking of milestones/deliverables and monitoring of resources and budget requirements

Problem Solving and Impact:

- Works on complex problems that require analysis or interpretation of various factors.
- Exercises independent judgment in determining methods and techniques to accomplish results.
- Recognizes that decisions could have a major impact on management and operations of an area within the department.
- Determines and develops plans and procedures on new assignments and may direct the work of others.

Position Requirements

Education: Bachelor's degree or its international equivalent. Focus on Education, Health, Behavioral, Life or Social Sciences, International Development, Human Development or related field preferred. In

lieu of a degree, an equivalent combination of education and relevant work experience is required.

Preferred Job-related Experience: Requires 7+ years of clinical research experience including assisting with protocol development, clinical monitoring, study implementation, study closeout, project management, analysis and reporting. ACRP or SoCRA certification required. Project or technical leadership experience required. Articulate, professional, and able to communicate in a clear, positive manner with clients and staff.

Additional Eligibility Qualifications: Technology to be used: personal computer, Microsoft Office (i.e. Word, Excel, PowerPoint, Outlook, SharePoint, Teams, etc.), e-mail, telephone, printer, calculator, copier, cell phones, PDAs and other handheld devices.