Hart Clinical Consultants
P.O. Box 510482
Melbourne Beach, FL 32951

Position/Title: **Principal Clinical Research Associate**

Job Description:

Acts as project resource to the clinical site, sponsor, and HCC personnel regarding the product under test and the clinical trial conduct. Drives the development and maintenance of company and departmental processes and procedures. Serves as Lead Monitor on assigned clinical trials to ensure adherence to Federal regulations, clinical protocol, company policies, and any other applicable procedures. May function as project manager to drive the clinical trial from start-up to completion.

Site Management / Compliance:

- Ensures compliance with protocol and all regulatory policies, procedures and/or guidelines during clinical studies by training/guidance of investigators/research coordinators, conducting periodic on-site evaluations and follow-up of corrective actions.
- Ensures validity of trial information by monitoring and tracking clinical trial data (CRFs, source documents, diagnostic reports, inventory logs, etc.) to identify/resolve discrepancies and obtain missing data.
- Maintains expertise in clinical trial regulations for applicable geographies and types of studies. Serves as a resource related to clinical trial regulations.
- Serves as a mentor for new employees and less experienced staff.
- Ensures timely collection of trial documentation by obtaining, maintaining and controlling all necessary records and documentation according to procedures and regulations.
- Ensures proper supply, accountability and storage of investigational product.
- Drives trial enrollment and identifies and communications potential and actual obstacles to enrollment.
- Identifies, evaluates, reports and ensures follow-up of adverse experiences by timely and accurate documentation and appropriate communication of all Adverse Event reports per internal procedures and regulatory requirements.
- Attends investigational cases as needed. Develops and maintains strong knowledge of specific trial therapeutic area and competitive landscape.

Clinical Operations:

- Manage site start-up activities; implements trial master file for tracking of site related documents.
- Reviews and approves clinical site-specific informed consents. Acts as a resource to other CRAs during the consent approval process.
- Trains contract research organizations (CROs) and other ancillary organizations.
- Ensures adherence to applicable ethical, regulatory, and clinical standards by leading the creation, review, and approval of departmental operating procedures, code of ethics, and mission statement.
- Represents HCC and/or sponsor Clinical Affairs Department on cross-functional meetings and projects.
- Identifies, evaluates, and collaborates with sponsor to qualify investigators, clinical sites, and CROs.
- Performs vendor and clinical site quality audits.
- Reviews and approvals interim monitoring reports; tracks monitoring progress and adherence to monitoring plan.
- Oversee vendor management activities (e.g. core imaging labs, central labs, CROs).

- Understands business environment and relates extensive knowledge of internal and external activities to trends. Interfaces with a variety of management levels on significant matters, often requiring the coordination of activity across organizational units.

Project Management:

- Drives the development of clinical protocols, plans, charters, case report forms, informed consent templates, and other trial aids.
- Leads project team; drives cross functional collaboration to complete projects.
- Develops trial timeline including major milestones (e.g. start-up, first enrollment, data snapshots).
- Develops trial reportable metrics and provides regular status updates to Sr. Management.
- Anticipates issues, develops and implements preventive actions or CAPAs as needed.

Skills/Experience:

Minimum Qualifications:

8+ years of related work experience with a strong knowledge of specified functional area, or an equivalent combination of education and work experience.

Preferred Qualifications:

10+ years of related work experience with expert understanding of specified functional area, or an equivalent combination of education and work experience.

Education/Certification:

Minimum Qualifications:

RN, RT, or associate's degree.

Preferred Qualifications:

RN, RT, and bachelor's or advanced degree preferred in scientific or technical field. Clinical Research Certification (ACRP, SoCRA).

Physical Demands/Work Environment:

50-75% primarily regional travel, however may be required to travel nationally, outside of specified region.