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

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

Job Description:

Acts as project resource to clinical site, sponsor, and HCC personnel regarding the product under test and the clinical trial conduct. Under management supervision, monitors assigned clinical trials to ensure adherence to Federal regulations, clinical protocol, company policies, and any other applicable procedures.

- Assist with site start-up activities, including collection of site personnel documents and with supervision, review of clinical site-specific informed consents.
- 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.
- 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.
- Maintains working knowledge of 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.
- 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.
- Ensures adherence to applicable ethical, regulatory, and clinical standards by participating in the creation, review, and approval of departmental operating procedures, code of ethics, and mission statement.
- Identifies and evaluates qualified investigators, investigational sites, and CROs.
- Attends investigational cases as needed. Develops and maintains knowledge of specific trial therapeutic area and competitive landscape.

Skills/Experience:

Minimum Qualifications:

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

Preferred Qualifications:

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

Education/Certification:

Minimum Qualifications:

RN, RT, or associate's degree. Scientific or technical degree preferred.

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 domestically or internationally, outside of specified region.