Senior Clinical Research Associate (Sr. CRA)

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Ensure that the clinical trials are being conducted in accordance with the clinical protocol, national regulations, international standards, and Second Sight procedures.
- Liaise with site personnel regarding the conduct of Second Sight clinical trials.
- Participate as a member of a team responsible for site qualification, site initiation, and site close-out visits.
- Set up clinical trial sites, which includes:
    - Support the assembly and submission of IRB/IEC applications by the sites
    - Support the assembly and submission of FDA/Competent Authority applications if/as needed (e.g. by supplying the site related information)
    - Prepare site initiation packets
    - Ensure that each site has the start-up kits and appropriate trial materials on a regular basis.
- Perform interim site monitoring visits which involve travelling to trial sites on a regular basis.
- Audit and verify that data entered on to the case report forms (CRFs) are complete, accurate, and consistent with patient clinic notes, known as source data/document verification.
- Manage queries and the data clarification process (DCFs) as guided by Data Management
- Ensure that all adverse events are reported in accordance with the required time frames for reportability.
- Review study documentation to ensure that subjects' rights, safety and welfare are being protected.
- Verify that all study logs and forms are being properly maintained at the site.
- Collect completed CRFs from trial sites.
- Write visit reports and follow-up on open action items to ensure appropriate and timely closure.
- File trial documentation, correspondence and reports.
- Ensure accountability of all investigational devices at the site.
- Review site regulatory documents for accuracy and completeness.
- Participate in the design of case report forms, informed consent forms and clinical protocols.
- Participate in the writing and reviewing of departmental operating procedures and standard operating procedures related to the clinical department.
- Assist with in-house data entry and filing, as necessary.
- On-site monitoring of current clinical trials as required by the company (20% of time)
- Primary responsibility for managing adverse events and safety review by the safety oversight body (e.g. Independent Medical Safety Monitor) in consultation with the Director of Clinical Affairs
- Enters safety data and IMSM adjudications into the clinical database.
- Prepares reports of serious adverse events to regulatory agencies
- Prepares routine safety reports to regulatory agencies and associated correspondence, and submissions

EDUCATION / CERTIFICATION: Bachelor's degree required with at least 7 years experience in the functional aspects of clinical trials.

EXPERIENCE REQUIRED: 2-3 years of experience in, or exposure to, clinical safety information management, preferably with Class III devices, or equivalent combination of education and experience.

REQUIRED KNOWLEDGE:

- Working knowledge of US / OUS medical device regulations, such as FDA QSR, FDA IDE/PMA regulations, and the European Active Implantable Medical Device Directive.
- Understanding of FDA compliance and GCPs.

SKILLS/ABILITIES:

- Excellent people skills, team oriented
- Effective written and verbal communication skills
- Detail-oriented with strong organizational skills
- Strong computer skills (word processing and database programs)
- Must be self-managing in prioritizing and delivering tasks against the departmental goals and requirements