



**Position: Senior Clinical Research Associate**

**Reports To: Director of Clinical Operations**

**Type of Position: Full time**

**Department/Business Unit: Study Management**

**Definition:** Under the direction of the Director of Clinical Operations, is responsible for monitoring clinical studies at investigational sites. Monitors those sites in order to ensure that studies are carried out according to protocol and in accordance with JSS SOPs, applicable regulations and the principles of Good Clinical Practice. Provides a benchmark of monitoring competence to inexperienced colleagues.

**Essential Functions:** The following duties represent the principle job duties however they are not all inclusive:

- ❑ Familiarity with JSS Medical Research SOPs and appropriate regulations
- ❑ Independently or in consultation with the Sponsor/JSS/CRO, coordinate all the necessary activities required to setup and monitor a study, including but not limited to the following:
  - Select investigators appropriate for the therapeutic area and protocol.
    - Assess study site to ensure, facility, patient population and staff are sufficient to support the protocol.
    - Meet with PI and staff to review study requirements (protocol, CRFs, Sponsor policy and procedures, investigator responsibilities, staffing and patient recruitment.
  - Conduct study initiation visit
    - Confirm appropriateness of the IRB/ethics committee.
    - Collect and forward all required study documentation to Sponsor.
    - Document visit.
  - Conduct routine monitoring visits to include:
    - Review protocol compliance.
    - Review CRF/source documents.
    - Resolve questions by Investigator/Staff
    - Check/inventory clinical supplies
    - Review communication with the IRB/ethics committee
    - Review study product accountability
    - Validate Informed Consent
    - Follow-up on previous issues
    - Submit all collected documents and site visit reports to Sponsor
  - Conduct close out visits to include:
    - Review and collect remaining CRFs.



- Retrieve clinical supplies and any other study materials
- Review investigator's files to insure that all documents are in order and ready for audit or inspection
- Review retention policy and publication procedure
- Review any follow-up requirements that may be required.
- Assist the Sponsor/JSS in problem solving and provide consultation on monitoring and study related activities.
- Keep the project manager informed

**Skills and Qualifications:**

• *Knowledge of:*

- MS Office
- Requirements for Good Clinical Practices
- Requirements for Good Documentation Practices
- 21 CFR Part 11 for Handling of Electronic Records

• *Ability to:*

- Travel at least 80% of the time (international and domestic: fly and drive)
- Maintain and exhibit discretion at all times when handling confidential information
- Make independent decisions and use good judgment
- Review and evaluate clinical data
- Plan, organize, and prioritize tasks efficiently
- Communicate effectively orally and in writing
- Assume multiple and concurrent tasks and responsibilities
- Establish and maintain cooperative and effective working relations with sites
- Demonstrate behaviors that are shared at JSS Medical Research: integrity, respect, professionalism, commitment, accountability

**Experience and Education:**

- Must have a minimum of a B.Sc. degree
- Minimum three years of clinical research experience, two years of which must have been as a working CRA. Experience will include study design and field monitoring.

Employee: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
(Print Name) (dd/ mmm/yyyy)

Supervisor: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
(Print Name) (dd/ mmm/yyyy)

