

Research Coordinator:

Job Description: List in order of importance.

Evaluate New Protocols for Feasibility

- Review protocols and other materials, such as Investigator Brochures and informed consent.
- Evaluate subjects' eligibility requirements and determine in the subject population will all appropriate recruitment to meet recruitment goals.
- Assess the ability to meet study timelines in light of other site commitments and overall feasibility.
- Assess the resources necessary to do the study, staffing, physical space, equipment, etc.
- Assess the financial feasibility of performing the study and negotiate contract with sponsor.

Preparing the Site for Conducting the Study

- Coordinate training for the research staff members
- Set up and organize study files
- Create and review study-specific source documents including but not limited to medical records and case report forms.
- Disseminate information about the study to the staff and physicians.
- Prepare documents for submission to the institutional review board (IRB).
- Collect documents needed to initiate the study and forward them to the sponsor or sponsor's agent.
- Attend investigator meetings.
- Clarify any concerns or issues with the sponsor.

Informed Consent Process

- Review consents for proper wording and communicate concerns or issues to the sponsor and/or IRB.
- Present the informed consent to potential subjects for review.
- Obtain subject's signature on the informed consent prior to any screening or treatment.
- Ensure that all necessary signatures and dates are on the informed consents.
- Documenting the informed consent process in patient research chart and filing these consents in secure location.
- Ensure that all amended consent forms are appropriately implemented and signed by subject, staff members and a witness.

Managing the Study Throughout the Trial

- Recruit, screen and contact potential subjects for the study.
- Schedule subject for screening, randomization, and follow-up appointments.
- Schedule subject with a variety of research staff members for testing.
- Prepare each study visit to ensure that appropriate study procedures are done.
- Assist the investigator and research staff members with study subject visits.
- Ensure all required data is collected and recorded at each study visit.

- Review case report forms for completeness, correctness, and logical sense.
- Identify and report adverse events and serious adverse events.
- Work closely with sponsor and monitors (CRA's) during site visits.
- Make corrections to case report forms; respond to queries.
- Ensure all study documents are current, complete and filed correctly.
- Manage laboratory procedures (draw blood samples, process samples, and ship samples).
- Perform ECG's as directed by sponsor and provide a copy of the results to the physician in a upon hardcopy of the results.
- Complete study closeout activities at the end of the study.
- Maintain regular communication with sponsor and/or CRO's and IRB's and investigators.

Job Experience/Knowledge and Education Level:

Required:

- Previous Research and/or COT Experience

Desired:

- Certified CCRA, C.O.T or Bachelors Degree

Skills/Behavior Characteristics:

- Flexibility – **High** level required
- Oral Communication - **High** level required
- Written Communication - **High** level required
- Delegation - **High** level required
- Leadership - **High** level required
- Initiative - **High** level required
- Stress Tolerance - **High** level required
- Sensitivity - **High** level required
- Analytical Skills - **High** level required
- Judgment - **High** level required
- Planning Organizing - **High** level required
- Morale - **High** level required

Additional Selection Criteria and/or Unusual Working Conditions/Equipment Utilized:

The coordinator must conduct all research studies according to the State and Federal regulations, along with ensuring the safety and well being of all the study subject throughout the study. Position requires a high degree of organizational skills, problems solving skills, and ability to communicate with a variety of people. Computer software literate

Performance Factors:

- Review study budgets for proper reimbursement.
- Review potential study patients for study participation.
- Respond to sponsors in a timely fashion.