JOB TITLE: Clinical Research Coordinator I

EMPLOYER: North Florida Foundation for Research and Education, Inc.

DEPARTMENT: Clinical Trial Center

REPORTS TO: Clinical Research Manager/Program Specialist

EFFECTIVE DATE: 2020

SUMMARY: The Clinical Research Coordinator I actively participates in clinical trials and is responsible for providing expertise as a clinical coordinator of his/her assigned studies under the direction of one or more Principal Investigator(s).

DUTIES AND RESPONSIBILITIES:

- Supports the enrollment of patients into clinical trials through recruitment, screening, enrollment and follow up of eligible subjects according to protocol requirements.
- Collaborates with the principal investigator to meet or exceed study enrollment.
- Reviews the study design and inclusion/exclusion criteria with physician and patient.
- Ensures the protection of study patients by verifying informed consent procedures and adheres to protocol requirements/compliance and provides close monitoring of subjects while on study.
- Ensures the integrity of the data submitted on Case Report Forms or other data collection tools by careful source document review. Monitors data for missing or inaccurate data and respond to queries.
- Creates study specific tools for source documentation when not provided by sponsor.
- Collects, completes, and enters data into study specific case report forms or electronic data capture systems.
- Generates and tracks drug shipments, device shipments and supplies as needed.
- Assists with sample collection to include environmental sample collection, packing and shipping of samples.
- Assists with study relevant forms required for various regulatory and oversight committees.
- Reports and follows up on serious adverse events as necessary.
- Implements study-specific communications.
- Maintains accurate and complete records including regulatory documents when applicable, signed informed consent forms, source documentation, drug dispensing logs, device utilization logs, subject logs and study-related communications.
- Tracks and reports adverse events, serious adverse events, protocol waivers, deviations, and violations.
- Attends study specific on site meetings, Investigator meetings, conference calls and monthly CRC meetings as required or asked to do so.
- Apprises principal investigator of all study specific medical issues for guidance.
- Assists Sponsor, VA, FDA, IRB and other audit teams as needed.
- Reviews and responds to any monitoring and auditing findings
- Maintains patient confidentiality according to ethical and legal requirements.
- Assists in providing coverage for other projects and investigators as necessary or when asked to do so.
- Performs other related duties as assigned by management.

SUPERVISORY RESPONSIBILITIES:

- This job has no supervisory responsibilities.

QUALIFICATIONS:

- Bachelor's Degree (BA) from four-year college or university, or two years of related experience and/or training, or equivalent combination of education and experience.
- Certificates, licenses and registrations:
  - Specialty research certification such as ACRP's CCRA, CCRC, ACRP-CP or SOCRA's CCRP are preferred, but not required.
- Computer skills required: Microsoft Office Suite
- Other skills required:
  - Working knowledge of medical and research terminology.
  - Working knowledge of federal regulations for human subject protections and Good Clinical Practices (GCP).
  - Ability to communicate and work effectively with a diverse team of professionals.
  - Excellent organizational and prioritizing capabilities.
  - Strong computer skills with demonstrated abilities using clinical trial database, electronic data capture.
  - Excellent interpersonal skills, detailed -oriented and meticulous.
  - Excellent professional writing and communication skills.
  - Ability to demonstrate proficient achievement of 'Entry Level CRC' based on ACRP Core.
  - Specimen and/or tissue collection, handling & processing.

COMPETENCIES:

- **Diversity** - Demonstrates knowledge of EEO policy; Shows respect and sensitivity for cultural differences; Educates others on the value of diversity; Promotes a harassment-free environment; Builds a diverse workforce.
- **Ethics** - Treats people with respect; Keeps commitments; Inspires the trust of others; Works with integrity and ethically; Upholds organizational values.
- **Project Management** - Develops project plans; Coordinates projects; Communicates changes and progress; Completes projects on time and budget; Manages project team activities.
- **Quality** - Demonstrates accuracy and thoroughness; Looks for ways to improve and promote quality; Applies feedback to improve performance; Monitors own work to ensure quality.
- **Teamwork** - Balances team and individual responsibilities; Exhibits objectivity and openness to others' views; Gives and welcomes feedback; Contributes to building a positive team spirit; Puts success of team above own interests; Able to build morale and group commitments to goals and objectives; Supports everyone's efforts to succeed.

PHYSICAL DEMANDS AND WORK ENVIRONMENT:

- Occasionally required to stand, walk, sit, utilize hand and finger dexterity climb, balance, bend, stoop, kneel or crawl
- Occasionally required to work around fumes, airborne particles, or toxic chemicals
- Frequent exposure to bloodborne and airborne pathogens or infectious materials
- The employee must occasionally lift and /or move more than 5 pounds
- Additional remarks regarding work environment:
  - This position is located within the North Florida/South Georgia Veterans Health System (NF/SGVHS) and specifically at the Malcom Randall VA Medical Center (VAMC), Gainesville, FL.
  - May be responsible for coverage after hours and/or on weekends as necessary, depending on the assigned projects and protocol requirements.

- Specialized equipment, machines, or vehicles used: EKG, centrifuge, vitals monitoring equipment, phlebotomy equipment, and other related study procedure devices.

The above is intended to describe the general content of and requirements for the performance of this job. It is not to be construed as an exhaustive statement of duties, responsibilities or physical requirements. Nothing in this job description restricts management's right to assign or reassign duties and responsibilities to this job at any time. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

ACKNOWLEDGEMENT (*Optional*)

I have read the foregoing job description and understand the responsibilities of the job. I agree that I am able to perform the essential duties of this position.

_____	_____
Employee Name	Manager Name
_____	_____
Employee Signature	Manager Signature
_____	_____
Date Signed	Date Signed