JOB TITLE: Clinical Research Nurse Coordinator III

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 Nurse Coordinator III applies the nursing process in the care and safety of research subjects and overall management of the protocol. Coordinates clinical studies; compiles, enters, reviews and assesses data for clinical studies; screens and recruits subjects. The Clinical Research Nurse Coordinator coordinates his/her assigned studies and works with other research team members 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.
- Reviews clinical records/charts and other records for clinical intervention, medication, and patient responses.
- Ensures the protection of study patients by verifying informed consent procedures and adhere to protocol requirements/compliance and provide close monitoring of subjects while on study.
- Compiles and enters clinical data into database; reviews and assesses data collected; collaborates with Investigator and other members of the study team; ensures timely and accurate data completion; submits documentation and correspondence for compliance with protocols; collects, completes, and enters data into study specific case report forms or electronic data capture systems; 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 responds to queries.
- Creates study specific tools for source documentation when not provided by sponsor.
- Generates and tracks drug shipments, device shipments and supplies as needed.
- Assists with sample collection to include phlebotomy, sample collection, packing and shipping of samples.
- Administers medications and experimental treatments within scope of license and practice.
- Obtains patient medical history, medication history, monitor and report patient safety concerns.
- 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; report and follow up on serious adverse events as necessary.
- Communicates all protocol-related issues to appropriate study personnel and regulatory entities.
- 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.
- Practices and adheres to NFFRE policies and VA rules for behavior.
- 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 in nursing, or six years of related experience and/or training, or equivalent combination of education and experience.
- Certificates, licenses and registrations required:
    - Certificate from an accredited RN or LPN program, with active Florida license in good standing
    - Specialty research certification such as ACRP's CCRA, CCRC, ACRP-CP or SOCRA's CCRP
- Computer skills required: Microsoft Office Suite
- Computer skills preferred, but not required: electronic medical record systems (EMR), electronic data capture systems (EDC)
- Other skills required:
    - Working knowledge of specialized medical/scientific terminology.
    - Knowledge of medication and proper dosages.
    - 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 with attention to detail.
    - Strong computer skills with demonstrated abilities using clinical trial database, and electronic data capture.
    - Excellent interpersonal skills and communication skills.
    - Ability to demonstrate proficient achievement of 'Senior CRC' based on ACRP Core
    - Phlebotomy experience.
    - 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.
- **Interpersonal Skills** - Focuses on solving conflict, not blaming; Maintains confidentiality; Listens to others without interrupting; Keeps emotions under control; Remains open to others' ideas and tries new things.
- **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.
- **Written Communication** - Writes clearly and informatively; Edits work for spelling and grammar; Varies writing style to meet needs; Presents numerical data effectively; Able to read and interpret written information.

PHYSICAL DEMANDS AND WORK ENVIRONMENT:

- Occasionally required to stand, walk, sit, utilize hand and finger dexterity, climb, balance, bend, stoop, kneel or crawl
- Occasionally 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.

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