**POSITION DESCRIPTION**

*Bay Pines Foundation*

1. **Position Title**: Clinical Research Coordinator
2. **Position Summary**: The Clinical Research Coordinator 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). This position is located within the Bay Pines VA Healthcare System (BPVAHCS), Bay Pines, FL. The incumbent will be an employee of Bay Pines Foundation, Inc., a nonprofit corporation partnering with BPVAHCS in support of VA’s research and education missions.

1. **Major Duties**:
* Support the enrollment of patients into clinical trials through recruitment, screening, enrollment, and follow up of eligible subjects according to protocol requirements.
* Collaborate with the principal investigator to meet or exceed study enrollment.
* Review the study design and inclusion/exclusion criteria with physician and patient.
* Ensure the protection of study patients by verifying informed consent procedures and adhering to protocol requirements/compliance, and further by closely monitoring participants while on study.
* Ensure timely and accurate data completion.
* Ensure the integrity of the data submitted on Case Report Forms or other data collection tools by careful source document review. Monitor data for missing or inaccurate data and respond to queries.
* Ensure that adequate and accurate record maintenance.
* Create study specific tools for source documentation when not provided by sponsor.
* Generate and track drug shipments, device shipments and supplies as needed.
* Assist with sample collection to include environmental sample collection, packing and shipping of samples.
* Assist with study relevant forms required for various regulatory and oversight committees.
* Report and follow up on participant serious adverse events as necessary.
* Implement study-specific communications.
* Ensure timely adherence to protocol requirements.
* Complete required documentation according to site work guidelines.
* Maintain 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.
* Track and report adverse events, serious adverse events, protocol waivers, deviations, and violations.
* Communicate all protocol-related issues to appropriate study personnel or manager.
* Attend study specific on site meetings, Investigator meetings, conference calls and monthly CRC meetings as required or asked to do so.
* Apprise principal investigator of all study specific medical issues for guidance.
* Assist Sponsor, VA, FDA, IRB and other audit teams as needed.
* Review and respond to any monitoring and auditing findings
* Maintain patient confidentiality according to ethical and legal requirements.
* Assist in providing coverage for other projects and investigators as necessary or when asked to do so.
* May be responsible for coverage after hours and/or on weekends as necessary, depending on the assigned projects and protocol requirements.
* Practice and adhere to the "VA Rules of Behavior."
* Complete all training assignments by the due date.
1. **Required Qualifications:**

*KNOWLEDGE, SKILLS, & ABILITIES* - This position requires the following minimal requirements:

· 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, and MS Word or Excel.

· Excellent interpersonal skills, detailed-oriented, and meticulous.

· Excellent professional writing and communication skills.

· Ability to work independently in a fast pace environment with minimal supervision.

*EDUCATION*

· Bachelor’s degree preferred, ideally in science, education, or health related fields.

· Nursing and/or phlebotomy background helpful, but not required.

*EXPERIENCE*

· 1-2 years healthcare-related experience is preferred (clinical and/or research)

*BACKGROUND SCREENING*

· The incumbent will operate under a WOC appointment at BPVAHCS, requiring a successful

background screening as a condition of hiring.

1. **Physical Demands**

Typically the employee may sit comfortably to perform portions of the work. However, there is periodic walking; standing; bending; carrying of light items such as office supply equipment and regulatory materials. No special physical demands are required to perform the work.

1. **Customer Service**

Meets the needs and consistently communicates and treats all Bay Pines Foundation customers, Bay Pines Foundation and VA staff, VA Investigators, research team members, veterans, their representatives, and visitors in a courteous, tactful and respectful manner. Provides the customer with consistent information according to established policies and procedures. Handles conflict and problems in dealing with customer constructively and appropriately.

*Bay Pines Foundation is an EEO Employer.*

For consideration, please send a resume and cover letter to:

Eric N. Abercrombie

Executive Director, Bay Pines Foundation

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