Community Research Site Mgr. - Long Beach

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Position Summary:

To be part of Research Operations at City of Hope, every employee should understand and share in the COH Vision, support our Mission, and live our Values. These values which include integrity, urgency, patient-centric focus, respect, accountability, and compassion—must guide what we do, as individuals and professionals, every day. To accomplish this, offering clinical research to our patients in our research satellites is essential. Clinical trials are a key research tool for advancing medical knowledge and patient care at city of Hope. The time it takes to activate a clinical trial is a key metric for comprehensive cancer centers; it allows COH to monitor and eventually drive both operational and financial clinical research improvements as well as reinforce public perception of COH as a leading institution in providing access to cutting-edge clinical research for patients and industry alike. The Community Research Site Manager (CRSM) works collaboratively with physicians, clinical research staff and the clinical staff to coordinate care for an assigned population of patients who are enrolled on an IRB clinical research trial that has been endorsed and opened in the community satellites. The CRRSM assists in the management and coordination inherent in the research studies across the continuum of care (outpatient, inpatient and home) including triage of phone calls and proactive patient communication at the multidisciplinary hub. The CRRSM serves to educate patients and families on the clinical trial treatments and required testing and is responsible to assure that the documentation for the clinical trial is completed and accurate. The Community Research Site Manager (CRSM) provides consistent leadership and general oversight of the daily research activities of the multidisciplinary hub and the research staff (CRC's, Regulatory Associate research scheduler, and research financial counselor) to ensure competent and standardized practices that are compliant with all institutional and regulatory requirements. The CRSM supports research operation strategic priorities to enhance interdepartmental communication and collaboration and assist in the development of best practices and tools for protocol execution, management and oversight as well as ensure, protocol compliance, quality data collection and compliance with Service Level Agreements (SLAs). The candidate has a significant impact on the ability to effectively manage clinical studies and develop the pipeline, while maintaining local regulatory and compliance requirements. S/he is able to make decisions

Community Research Site Manager independently and oversee important activities relevant to clinical research activities at the multidisciplinary hub with the support, oversight and supervision of the VP, Clinical Research Operations. The candidate requires a strong understanding of clinical trial planning, management and metrics as well as the ability to focus on multiple deliverables and protocols simultaneously. S/he needs strong leadership skills (scientific and business) and the ability to coordinate and lead teams to high performance. The candidate must work to build and maintain

relationships with faculty that reside within the hub(s) they serve, external partners, faculty and staff at the Duarte campus and promote COH's reputation. The candidate is accountable for the performance of and adherence to assigned protocols in compliance with ICH/GCP regulations, institutional policies and procedures, quality standards and adverse event reporting requirements internally and externally. The candidate is the point of contact for the operational and research support required for assigned protocols and pro-actively drives/tracks execution and performance of deliverables/timelines/results to meet institutional commitments for assigned protocols. S/he will be responsible for quality and compliance in assigned protocols and oversees CRCS, Regulatory Associates, Schedulers/financial counselors and CRN's. S/he will need to collaborate with functional outsourcing vendors, investigators, other external partners and will collaborate internally with the Regional Medical Lead and the Community Practice Senior Medical Director.

Key Responsibilities include:

Planning and Goal Setting

• Create and implement policies and procedures to ensure work standardization within the community hubs that is strategically aligned with the Duarte campus and optimizes the clinical network.

• Utilize rounding boards and staff huddles to support enterprise clinical research goals. Support the strategic plan for the organization and for clinical research. Support departmental implementation of new technology (OnCore) and services.

• Build and sustain relationships with internal and external stakeholders.

• Retrieve and deliver pertinent reports to leadership as requested. Effectively communicate (written & oral) across the enterprise. Serve on working groups to enable City of Hope to meet its strategic goals.

Quality Research Oversight

• Responsible for ensuring protocol compliance by staff and providing recommendations for corrective action when necessary. Communicate and escalate unresolved issues at the appropriate time to the appropriate level of management.

• Assist in the management and coordination of all aspects of care as defined by the protocol and communicates this through education with the patient and/or family regarding treatment plan, testing requirements, and follow-up care. Consistently communicates this to the physician and other health care professionals and research team members.

• Meet regularly with disease program leaders, regional hub research lead, community faculty investigators and clinical research leadership to provide necessary updates.

• Identify and initiate improvements, tools, processes, and forms to enhance the efficiency and the quality of work. Lead the preparation for external audits in collaboration with DQM.

Community Research Site Manager

• Assist in the review of audited protocols for adherence work with the research team to construct responses to the audit report. Meet with internal and external monitors to communicate any issues or challenges and develop corrective action plans as needed.

• Provides input in the development of departmental Policies and Procedures.

• Collaborates with Research Operations Leadership to lead, manage and document performance improvement projects.

Personnel Management

• Support efforts to recruit and maintain an adequate number of competent staff to conduct clinical research in compliance with all regulatory, institutional and departmental requirements.

• In collaboration with clinical research leadership and the regional research lead, develop, maintain and monitor staffing plan for assigned teams. Monitor time and effort tracking reports on a periodic basis and review with Portfolio Supervisor as needed.

• Collaborate with human resources to provide counseling or performance improvement of staff as needed.

• Manage and lead staff to develop collaborative working relationships within the department, clinical operations within the community and with other departments as applicable.

• Attends all pertinent departmental COH and Working Group meetings.

Fiscal and Budget

• Provide input for the annual budget preparations. Develops quarterly and annual staffing plan in collaboration with Leadership

• Collaborate with clinical research leadership to identify community practice disease team needs on a monthly as well as annual basis. Participates in operational and feasibility assessments to support community research within the disease programs.

• Develop, manage and report on community participation in the Disease Team portfolio measures. Provide input and support to Research Operations Leadership in the development of new programs or services to support research accruals in the community.

• Identifies and communicates opportunities for improved efficiency and/or cost saving within the department. Provide documentation to support the purchase of equipment, supplies and/or for department repairs.

Enterprise Management

• Work in conjunction with the disease team program lead physicians, Principal Investigators, community faculty, Regional Research Lead and Leadership to accomplish goals, projects and research initiatives for assigned disease teams

• Collaborates across multidisciplinary teams and provides guidance, direction and management to clinical research staff working in the community regional hub

• Develops corrective action plans (CAPAs) as needed. Develops working relationships with study sponsors for future collaborations

• Follows established City of Hope and department policies, procedures, objectives, performance improvement, attendance, safety, environmental, and infection control

Basic education, experience and skills required for consideration:

- Bachelor of Science in Nursing
- Five years of clinical research experience
- Thorough knowledge of Good Clinical Practice, Human Subject Protection, clinical trial design, regulatory processes, and clinical development process.
- Ability to collaborate with internal and external stakeholders across functions to optimize performance and drive projects to completion.

Required Certification/Licensure:

- Current California RN license; American Heart Association BLS Certification

Preferred education experience and skills:

- Master of Science in Nursing
- CCRP, Oncology Nurse Certification (OCN, AOCN, AOCNS, or AOCNP) and certification by the Association of Clinical Research Professionals (ACRP) or the Society of Clinical Research Associates (SoCRA).
- Five to ten years clinical research and supervisory experience, oncology preferred.

Additional Information:

As a condition of employment, City of Hope requires staff to comply with all state and federal vaccination mandates.

- Full-time
- Days

City of Hope is committed to creating a diverse environment and is proud to be an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, religion, color, national origin, sex, sexual orientation, gender identity, age, status as a protected veteran, or status as a qualified individual with disability.