NON-CONTRACT ROLE DESCRIPTION

JD3464

ROLE TITLE:	Clinical Research Manager	**ROLE DESCRIPTION NO.:**	01095
DEPARTMENT:	Research and Capacity Building	**HEABC REFERENCE NO.:**	1872843
REPORTING TO:	Director, Research Support Services	**HSCIS CODE:**	04080
CLASSIFICATION:	NCEM/Range 9	**JOB CODE:**	04230AH

ROLE SUMMARY

In accordance with the Vision, Purpose, and Values, and strategic direction of the Vancouver Island Health Authority, patient safety is a priority and a responsibility shared by everyone at VIHA; as such, the requirement to continuously improve quality and safety is inherent in all aspects of this position.

Working under the direction of the Director, Research Support Services, the Clinical Research Manager provides leadership and implementation support for the conduct of clinical research in compliance with applicable regulations, contractual agreements and quality standards. The Clinical Research Manager, working with Principal Investigators and Research Coordinators, will have a primary responsibility for business development management, mentorship and human resource planning and optimizing VIHA s performance in trial start up, implementation and close out.

DUTIES AND RESPONSIBILITIES:

1. Oversees the daily activities of departmental research staff with respect to performance, efficiency and compliance to contractual requirements, study protocols, applicable regulations and research ethics requirements in the conduct of clinical research.

2. Assists in the development of Standard Operating Procedures (SOPs) for key clinical research activities to ensure regulatory compliance and standardized, efficient business processes. Implements corrective actions in response to protocol, regulatory or SOP deviations and preventative actions in cases where the potential for non-compliance is identified.

3. Ensure that clinical research staff are trained in accordance with their job requirements. Provides mentorship to clinical research staff and participates in the development of educational symposia, workshops and training tools.

4. Reviews monitoring reports and conducts appropriate follow up with research staff on significant or problematic issues. Collects and reports key performance metrics, including compliance statistics, for each study to the Director, Research Support Services.

5. In collaboration with study teams or Investigators, the Manager is responsible for centralized tracking the receipt of feasibility questionnaires for new trials, ensuring their timely completion and reporting on the success of new study acquisition as required by the Director to maximize VIHA's success in being selected for new trials of scientific interest of investigators and potential benefit to patients. Assists and participates in the organization of pre-site selection and qualification visits and actively promoting VIHA's strengths as a research site.

6. Proactively implements marketing and business development strategies, in close collaboration with physicians (Principal Investigators) and research coordinators, in existing and new therapeutic areas of scientific and clinical importance to physicians, patients and VIHA. Working with existing study teams, facilitate strong working relationships with external stakeholders to increase repeat opportunities for studies and increase VIHA's reputation as a world-class destination for clinical trial conduct.

7. Networks extensively with members of external members of the research community, including at collaborating academic institutions, and participates on at least one task force within the BC Clinical Research Infrastructure Network.

8. Supports new Principal Investigators develop clinical research skills and expertise, make possible an increase in the number of Principal Investigators across therapeutic areas at VIHA and maintains strong and positive relationships with VIHA's Investigator community.

9. Working closely with Principal Investigators and existing study teams, write study protocols, informed consent forms and other implementation documents for Investigator-initiated clinical research. Facilitates completion of start-up regulatory and ethics documentation where required to ensure streamlined start up timelines.

10. Hires and manages human resources (including research coordinators) for new and existing studies to ensure that studies are operating in accordance with Sponsor, regulatory and ethical expectations for timeliness and quality.

11. Ensure that effective study-specific recruitment plans in conjunction with protocol requirements and research team input. Track and monitor recruitment success, implementing contingency plans were applicable or advising on feasibility of continuing participation.

12. Participate in the development of strategies, including education and outreach, to better engage the public in education regarding clinical research.

13. Participates in the development of study budgets, conducts regular reviews of research budget status and invoicing in collaboration with the Research Financial Coordinator. Ensures that Principal Investigators are provided with clear, transparent and regular reports on the financial status of their trials. Monitors study workload requirements to ensure that negotiated budgets are sufficiently covering study costs, facilitates or directly participates in renegotiation of study budgets with Sponsors, if required.

14. Engages study Sponsors in problem-solving discussions where operational problems potentially impacting resources or compliance arise with protocols, instructions, data collection tools or other technologies arise.

15. Performs other duties as assigned.

QUALIFICATIONS:

Education, Training And Experience

A level of education, training and experience equivalent to a bachelor's degree (minimum) in a health or health-research related field and seven to ten years experience in clinical research, including managerial responsibilities and leading change initiatives in a research-focused organization.

Skills And Abilities

- Demonstrated expert knowledge of the application of Good Clinical Practice guidelines and applicable (national and international) regulations related to clinical research conduct.
- Expert knowledge of human subjects protection, including a functional understanding of the requirements of the Tri-Council Policy Statement 2 (and tutorial completion).
- Ability to manage multiple concurrent projects, assess priorities and utilize resources effectively.
- Strong, supportive and enabling managerial and leadership skill.
- Well-developed written and verbal communication skills, including public speaking. Proven ability to communicate with diplomacy.
- Certification with the Association of Clinical Research Professionals or the Society of Clinical Research Associates is an asset.
- Demonstrated ability to lead change.
- Demonstrated ability to perform under explicit time restraints.
- Ability to perform risk assessments and prioritize action based on results.

- Demonstrated ability to maintain effective working relationships both internally and externally.
- Demonstrated ability to problem-solve under pressure.