UNION JOB DESCRIPTION

JD1038

JOB TITLE:	Research Nurse Coordinator	**JOB DESCRIPTION NO.:**	80074
CLASSIFICATION:	Program and Services - Profile Classification - Level 3	**GRID/PAY LEVEL:**	NL3
COLLECTIVE AGREEMENT:	Nurses Bargaining Association	**HSCIS NO.:**	23001
UNION:	BCNU	**JOB/CLASS CODE:**	80074
PROGRAM/DEPARTMENT:	Research and Capacity	**BENCHMARKS (If Applicable):**	
REPORTING TO:	Manager, Clinical Research or designate		
FACILITY/SITE:	Vancouver Island Health Authority (GRH, RJH, VGH, NRGH)		

JOB SUMMARY:

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

Reports to the Manager, Clinical Research or designate and is accountable to the Principal Investigator for each research trial. In accordance with the BC College of Nurses and Midwives standards for practice, code of ethics and patient care guidelines and the established vision and values of the organization, assesses patients in the clinics for entry into clinical research studies, coordinates clinical research trials in accordance with approved research protocols and ethics guidelines, and acts as a member of an interdisciplinary team conducting research and provided quality patient care. Liaises with internal and external sources to obtain required research approvals, report side effects of research treatment and provides documentation to patients and other health care professionals about the research protocol. Duties also include preparation of study documents such as informed consent documents, ethics submissions, patient screening, collection of study data and specimens, completion of all case report forms and administration of study treatment. Participates in investigator and study coordinator meetings and training sessions. Completes all work according to Food and Drug Association standards, Therapeutic Products Directorate and International Conference on Harmonization - Good Clinical Practice.

Hours of work are not regularly scheduled but are flexed in accordance with the trial the RN supports.

TYPICAL DUTIES AND RESPONSIBILITIES:

1. Assesses and screens subjects in the clinic(s) and hospital(s) for enrolment into clinical research studies by reviewing each research protocol, reviewing subjects diagnosis and test results, and collecting information from other health care staff as applicable per policy.

2. Designs and prepares documentation and forms such as data collection sheets, laboratory requisitions, physician orders, flow sheets, and checklists by using templates and word processing tools to make forms specific to each study for use during the study period.

3. Participates in the facilitation of informed consent of subject/family and assists physicians in enrolment of subjects by performing duties such as typing and revising consent forms specific to each study, assisting to explain to the subjects/family the nature of the study, potential side effects and their continued rights during the study period in order to obtain informed consent prior to commencement of study procedures.

4. Liaises with various internal and external offices including the Research Centre, other departments and pharmaceutical or granting agencies to coordinate receipt of required documentation and research approval, obtain authorizing signatures, and answer inquiries regarding the research studies.

5. Prepares various documents, in consultation with the Principal Investigator and Coordinator, Business and Regulatory Affairs, such as ethics submission documents for new clinical and research studies; study updates (Amendments); serious adverse events and other pertinent information required to be submitted to the ethics board.

6. Administers and/or oversees the administration of study drugs and required tests to subjects by drawing blood, assessing and evaluating subjects progress, symptoms and overall experience/reaction to study participation, recognizing and responding to anticipated and unanticipated participant responses to the study drugs, documenting assessments in appropriate hospital and research records and reporting adverse side effects and events to the Principal Investigator and research agency to ensure subject safety and research protocols are not compromised.

7. Completes required incident reports in accordance with professional standards and hospital policies.

8. Maintains research case report forms and protocol files by methods such as gathering required documentation, photocopying and filing information in the appropriate area, transferring source information from subject charts to required forms, visiting Health Records and contacting subjects and/or other health care facilities to obtain all necessary information for the research protocol.

9. Maintains adequate study supplies of medication, including maintaining drug accountability records, dispensing study medication, acknowledging receipt of study medication and returning study medication to sponsor as required.

10. Consults and collaborates with unit nurses and other interdisciplinary team members the coordination of research participation through methods such as presenting in-services on each study, maintaining protocol information binders on appropriate wards and troubleshooting and providing guidance and knowledge about research procedures and the integration of research participation with subject care.

11. Establishes therapeutic relationships with subjects and families, while adhering to professional boundaries as set out by the BC College of Nurses and Midwives standards of practice and Code of Ethics. Teaches outpatient subjects and families self administration of research medication where appropriate by discussing and demonstrating injection methods, explaining safety issues and potential side effects and regularly contacting participants to ensure compliance with treatments quantities and times and identify and discuss concerns/issues to the research treatment.

12. Ensures follow up consultations required by research protocols are conducted by tracking the time between visits, telephoning the subjects, scheduling visits to the clinic, advising the investigator of the assessments/tests that the research protocol requires and transferring assessment/test results into appropriate case report forms for completion.

13. Liaises with pharmaceutical or other research sponsoring bodies by methods such as providing feedback on case report form design, corresponding about status of the study, advising of side effects of study medication for subjects and meeting with research monitor/representative to review case report forms before, during and after the study to ensure protocol, research and ethics guidelines are met for each study.

14. Coordinates supplies required for each study by reviewing the research protocols contacting medical supply companies, ordering and receiving required supplies, and tracking resource utilization.

15. Prepares and ships blood for analysis by outside laboratories as required by the study by ordering shipping supplies and containers, packing the blood and making courier arrangements to ensure research protocol/procedures are followed. Additionally, collaborate with local laboratory(s) to draw/process the blood samples when necessary.

16. Maintains study documents in accordance with Health Canada and United States Food and Drug Administration policies.

17. Ensures practice is in accordance with International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use guidelines on Good Clinical Practice.

18. Participates on designated programs and professional committees/teams through methods such as attending meetings, drafting/revising documentation /forms for review by committee and providing written/verbal input to facilitate the resolution of issues and/or to advocate for the goals of the program.

19. Performs other related duties as assigned.

QUALIFICATIONS:

Education, Training And Experience

Registration with BC College of Nurses and Midwives as a practicing RN registrant with three years' acute care

experience and two years' experience as a clinical trial coordinator, or an equivalent combination of education, training and experience.

Skills And Abilities

- Broad knowledge of nursing theory and practice with a client/family centered model of care.
- Broad knowledge of BC College of Nurses and Midwives Standards for nurse researchers.
- Broad knowledge of the physiological and behavioral aspects of complex illnesses.
- Demonstrated knowledge in the shipping and handling of bio-hazardous materials and dangerous goods.
- Broad knowledge of research and clinical research methodology and data presentation.
- Demonstrated ability to work collaboratively as a member of an interdisciplinary team.
- Demonstrated ability to adjust to new or unexpected situations.
- Demonstrated ability to effectively deal with others in a consultative/collaborative method.
- Demonstrated self-direction and organizational skills.
- Demonstrated ability to organize and prioritize work.
- Demonstrated ability to work independently.
- Demonstrated ability to communicate effectively orally and in writing and deal effectively with subjects, and their families, coworkers, physicians, and other health care staff and staff of outside agencies.
- Demonstrated ability to counsel and teach subjects and their families.
- Demonstrated skill in the use of medical equipment and supplies appropriate to the area.
- Demonstrated computerized software skills in word processing, spreadsheet, databases, presentations and Internet access and ability to operate a computerized subject care information system.
- Demonstrated ability in CPR techniques.
- Physical ability to perform duties of the position.