

Job Class Profile: Research Registered Nurse Co-ordinator**Pay Level: NS-31 Point Band: 893-943**

Factor	Knowledge	Interpersonal Skills	Physical Effort	Concentration	Complexity	Accountability & Decision Making	Impact	Development and Leadership	Environmental Working Conditions	Total Points
Rating	6	6	3	5	6	6	5	3	3	
Points	280	100	19	24	180	130	103	64	32	932

JOB SUMMARY

The Research Registered Nurse Co-ordinator provides professional nursing leadership and administration of applied research activities. The work involves administering research activities, providing leadership in the development and implementation of research projects, co-ordinating, implementing, and maintaining clinical trials, developing and maintaining education programs, and co-ordinating, and supervising project terminations.

Key and Periodic Activities

- Visits patients enrolled in clinical studies, performs comprehensive medical history and evaluation, and/or testing (i.e. blood work, body measurements, Electrocardiogram, vital signs, etc.), collects data through in questionnaires, and processes and prepares any samples taken for shipping or storage.
- Counsel's patients regarding their participation in the research study including expectations such as how they will be monitored, how the information will be used, and explains any side effects, or relevant instructions that must be followed during the study.
- Reviews information collected, enters this into a database, and maintains and updates information as study progresses including any follow-up visits or adverse events.
- Coordinates and initiates research projects including preparing research application, consent information for submission to the ethics board; prepares project budget and liaises with sponsor and Office of Research for contract agreements, prepares proposal for resource allocation, plans and coordinates initiation meetings, attends study start up meetings, and makes any changes to protocol amendments or addendums.
- Recruits and screens patients for research projects; reviews charts, assesses patients for inclusion/exclusion criteria, and follows up with patients regarding responses from potential participants. Prepares advertising materials to recruit patients, organizes, and facilitates informed consent sessions with the investigator.
- Acts as the liaison between the investigator, sponsor and participant; communicates with the sponsor, ethics committee, other agencies, and facilitates the day-to-day activities of the research.
- Provides staff inservicing related to study protocols, patient eligibility, and functions as the resource person to promote an understanding of the goals and objectives of the research project.
- Coordinates appointments, schedules procedures for patients and appointments with investigator and study staff, and arranges follow up, as required.
- Prepares monitoring activities for research sponsoring companies, which involves providing

Key and Periodic Activities

- data, sources, reports, and reviews audits with monitor and investigator.
- Performs study closures activities such as resolves all outstanding questions from sponsor, ethics, and patients, arranges patient follow-up after post study, packs up case reports forms, study documentation, and arranges storage of data as required by regulatory bodies.
- Attends staff meetings; coordinates, and attends meetings for team members involved in study to discuss ongoing protocols, staffing issues, etc.
- Attends and participates in continuing education and in-services including study specific training as required.

SKILL

Knowledge

General and Specific Knowledge:

- Research area conditions, procedures, and treatments
- Nursing assessment
- Policies, procedures, standards of practice, and guidelines (i.e. regional, provincial, and national)
- Current knowledge of trends, and developments within nursing and specific study area
- Research, evidence based practice, and protocols
- Ethics, research protocols, and consent
- Clinical practice guidelines and the Tri-Council Policy Statement (TCPS) on the conduct of studies involving humans.

Formal Education and/or Certification(s):

- Minimum: Undergraduate Degree in Nursing from an approved college or university, and Registration with the Association of Registered Nurses of Newfoundland and Labrador (ARRNL)
- BLS certification
- Certification in Transportation of Dangerous Goods

Years of Experience:

- Minimum: 4 - 5 years of experience with at least 3 years in the research study area

Competencies:

- Effective oral and written communication skills
- Problem solving abilities
- Analytical, critical thinking and attention to detail
- Operate various types of equipment and machinery
- Proficiency in the use of various computer software packages to analyze statistics and write reports.
- Work in a multi-disciplinary team as well as independently.

Interpersonal Skills

- A range of interpersonal skills are used to perform activities such as listening and asking questions to gather information from participants in the study to assess their understanding and

compliance with the study protocol; providing direction, expert advice and communicating complex information to participants and other health professionals; instructing/training or counselling participants regarding condition, treatments, etc., and consulting with physicians, investigators, and sponsors regarding activities of the study.

- Communications occur with a range of contacts including participants involved in the study, employees within immediate work area, and department for coordination, planning, and delivery of research activities, the manager, government employees, sponsors, suppliers/contractors, sales representatives, and professional associations.
- The most significant contacts include research study participants, sponsors, supervisor or manager and staff involved in research studies and activities.

EFFORT

Physical Effort

- The demands of the job generally do not result in considerable fatigue nor does it require the need for strength and endurance.
- Occasionally lifts or moves objects up to 10 lbs (i.e. patient charts, lab supplies, boxes of supplies, paper, and binders).
- Regularly stands when reviewing patients' charts, performing assessment on participants and regularly sits to counsel participants, input data into a computer, develop reports, read, send emails, respond to correspondence and answer, or follow up with participants on the telephone where there is no restriction of movement. Occasionally is required to walk to different areas of the building to assess and counsel participants in studies.
- Occasionally performs some testing on patients and when doing so, often works in awkward or cramped body positions. Regularly uses fine finger movements when working with the computer mouse.

Concentration

- **Visual concentration or alertness** is required when working on the computer for extended periods to input data into a database, writing reports, assessing patients' condition and vital signs, to calculate and dispense medication, to give and teach participants how to give injections, take medications, and to read instruments (i.e. glucose meter).
- **Auditory concentration** is required to listen and provide information in person, on the telephone, and to be able to answer questions.
- **Other sensory demands such as touch** is required to give participants injections or to perform a physical assessment.
- **A higher than normal level of attentiveness** is required when counseling or discussing aspects of the research study with participants to ensure their understanding, compliance, and reporting of issues such as side effects, as these require immediate reporting.
- **Repetitive tasks which require alertness** occurs when providing advice and information to participants, when observing them for any side effects, adverse events, and their understanding of the study.
- There is **lack of control over the pace of work** during recruitment activities, as these activities require assessment of multiple participants and when there are **deadlines** to complete protocols, ethics submissions, etc. Work is subjected to **time pressures**, as all clinical trials involve specific timelines and deadlines. Other **time pressures are deadlines** for institutional review

boards, reporting of adverse events, and follow up of patients. Constantly has **interruptions** from participants requesting advice and guidance and sponsors requesting information or documents.

- **Eye/hand coordination** is essential when performing venipuncture, positioning of ECG leads, calibration of machines, to weigh and measure participants, and to use the computer keyboard to type.
- **Exact results and precision** are required when administering injections, interpreting test results or giving tests, when teaching participants about medications, equipment, and when preparing laboratory samples for storage or shipment.

Complexity

- Tasks and activities are different/unrelated and require the use of a broad range of skills and a diversity of knowledge.
- Complexity of the work varies. Tasks vary between being repetitive and well defined, to problems that must be defined and practical solutions found. Tasks are regularly different, but related where there are limited guidelines or procedures that exist and a limited opportunity for standardized solutions. Occasionally, tasks require creative problem definition, analysis, and solution development that may be solved in a team setting.
- Typical complexities include counselling and educating patients who are having difficulty with specific medical conditions, study protocols, and regularly investigating methods to help improve their situation. In addition, each clinical trial is complex and often vastly different, therefore would be responsible for a variety of different scientific studies at any given time.
- Complexities tend to be resolved through the use of available supports such as consulting with the principal investigator, healthcare professionals, and government departments; and following or reviewing clinical practice guidelines, regulations from FDA and Canadian Health governing bodies, ethics board, government regulations, and associations specific to study area, standards of practice, guidelines both provincial and federal regulations and Acts, code of ethics, ARNNL guidelines, department/organization manuals, journals, clinical or procedural textbooks; and policies and procedures.

RESPONSIBILITY

Accountability and Decision-Making

- Works independently within the program activities. Has the ability to make decisions related to patients eligibility for clinical trial, make medication adjustments based on the protocol, order day-to-day supplies, pay invoices for services (i.e. pharmacy fees, etc.) and have signing authority for grants. Also is responsible for the overall budget of the study, and prepares budgets for a particular study. Responsible to prepare applications and consent forms; however, these require approval from office of research and the ethics board.
- Would require prior approval for commitments such as contracts on behalf of the organization, to travel, and some approval is required for specific events related to patients' eligibility, or continuous eligibility in study.
- Exercises a high degree of independent discretion and judgment when consulting with or providing advice to patients in relation to potential adverse events. Exercises discretion and judgement to interpret directions and apply guidelines in decisions within the study protocol scope. Has some discretion to exercise within predetermined limits and procedures.

Impact

- Work performed has an impact in and outside the organization and on patients, as well as on resources such as equipment, information, facilities, finances, and health and safety. The most significant impacts are on the health and safety of patients, information, and finances.
- Work activities could either negatively or positively impact on the finances (i.e. errors or omissions in spending and negotiating the budget); patients (i.e. their safety if protocols are not followed correctly); and corporate image (i.e. when studies get recognition). The tasks are highly monitored or controlled due to the nature of its activities, which are based on the professional standards, protocols, and guidelines that must be in place for all applied research activities.
- Typical examples of mistakes or errors are a medication error (i.e. giving a participant the wrong medication or the wrong amount), or giving a participant the wrong return appointment. Requires licensure to practice and their professional activities are monitored through their professional association.
- Problems are typically identified and resolved within hours and could be detected by the Coordinator, other nurses, manager, or healthcare providers. Resolution may have an impact over the short-term or beyond.

Development and Leadership of Others

- Not responsible for the supervision of staff.
- Provides other development and leadership responsibilities such as on-the-job advice, guidance, feedback, orientation, and on the job training. Depending on the study and the need for additional staff, may provide coordination and direction of activities to an assistant.
- Does provide team and project lead roles in that they give expert advice to participants, health professionals, government agencies, community groups, and the manager related to the study. Also works on research projects in which they are the project leader for the activities of the study including collecting data, developing reports, ethics submission, proposals, etc., acting as an advisor to the investigators, sponsors, etc., and following all protocols, timelines, guidelines, etc.

WORKING CONDITIONS**Environmental Working Conditions**

- Occasionally, handles biological substances and are required to use protective equipment such as gloves/masks/gowns/goggles and to practice universal precautions.
- There is a limited likelihood of injury or illness or partial or total disability, if safety precautions are followed.
- Occasionally is required to travel, sometimes in adverse weather conditions. During research studies/activities, may be exposed to bodily fluids, waste, infectious diseases, odours, and sharp objects.