Job Description

(For Positions in CAW Local 555, Unit 1)

Job descriptions do not include every duty that an individual in a position performs. They are intended to be representative and characteristic of the duties required and the level of work performed. Depending upon the size of the department or unit and its functional activities, incumbents who fall into this category may perform all of the duties listed below or, in the case of large departments or units, may be assigned to designated specialized functions.

JD #:	**JD00647**	Pay Grade:	**10**
JD Title:	**Clinical Research Nurse (I)**	JD FTE Hours:	**35**
Job Family:	**Research Coordinator**		

General Description

Responsible for planning, assessing, implementing, and evaluating protocol procedures and managing the daily operations of clinical research studies ensuring that all aspects of the study protocol are adhered to. Coordinates all aspects of the project related to managing a patient from study entry to completion of a follow-up which includes coordinating other aspects of on-going care. Requires specialized, professional nursing care knowledge in the clinical area and knowledge of research principles and practices.

Representative Duties & Responsibilities

- Assume primary responsibility for the preparation and implementation of clinical research protocols.
- Participate with a team in the development and authoring of research protocols.
- Troubleshoot problems at all stages of project development and implementation and assist with modifying protocols or project procedures to address challenges.
- Interview patients and conduct physical and psychiatric assessments to determine eligibility for participation in research studies.
- Monitor patients for adverse reactions and be prepared to respond appropriately.
- Mediate with family members and caregivers who may be hesitant to have their family member involved in a study and educate them regarding the disease process and the benefits of clinical studies.
- Liaise between the clinic centre and remote clinic sites and personnel.
- Process information and have the knowledge base required to recognize problems with patients and intervene appropriately for the well being of the patient.
- Analyze and process information to ensure the accuracy and appropriateness of patient management.
- Ensure that the relevant research methodology is applied and all research material is handled in accordance with established protocols, policies, and procedures.
- Conduct and process study specific assessments of patients to determine suitability for projects and degree of disease acuity.
- Apply specialized knowledge and scientific principles to review, critically appraise and interpret published literature.
- Empathize with study patients and be attentive to their needs.
- Recruit patients and enlist agencies to refer patients.
- Review referrals and keep track of intakes from various referral sources.
- Design promotional strategies and related materials to encourage participation and support for the research study.
- Facilitate focus group sessions with study patients.
- Write sections of scientific papers, funding proposals, abstracts, and Research Ethics Board submissions.
- Design and develop various forms, data reports, and letters required for the study.
- Document and analyze patient responses and adverse events that may be experienced by a patient during the study.
- Document and maintain patient consult notes, assessments, drug accountability logs, charts, and histories on each patient.
- Plan and coordinate studies across multiple sites.
- Develop estimates of time and resources for research projects.
- Use statistical software to analyze data and interpret results.
- Complete various calculations such as medication doses, safety values for clinical testing, and drug formulas.
- Develop presentations and present information and training sessions to study personnel and patients.

Representative Duties & Responsibilities

- Retrieve and respond to results of diagnostic tests.
- Keep study participants informed of study progress through regular reports and newsletters.
- Implement and maintain study budgets. Create financial projections and make adjustments to study budgets throughout the fiscal year.
- Exercise appropriate controls, monitor, and reconcile accounts.
- Responsible for the accurate collection of relevant data and ensure that all events are identified and properly recorded and that necessary confidentiality is maintained.
- Collect, verify, evaluate, and record all patient study data.
- Update and maintain information in a variety of databases and spreadsheets.
- Gather, compile, and submit all pertinent documents such as physician and nursing licenses, curriculum vitae for all staff involved in the study, Food and Drug Administration forms, and Research Ethics Board documents, prior to the start of a clinical study.
- Arrange for the safe and orderly exit of patients from the study.
- Accountable to the College of Nurses of Ontario for all actions taken with study patients and must practice according to the Regulated Health Professions Act and the Standards of Practice for Nurses in Ontario.
- Conduct literature searches.
- May be required to perform specific medical procedures such as, venipuncture, pipetting samples, and administering medication by injection.
- May be required to set up and monitor various medical devices such as intravenous and electrocardiogram equipment.
- Collaborate with hospital administrators to facilitate the introduction of study protocol procedures within their departments.
- Coordinate the procurement of equipment, supplies and data collection forms.
- Inform patient and family about study protocols and procedures.
- Explain benefits, risks and schedules prior to obtaining informed consent. Obtain formal, informed, and signed consent.
- Abide by and adhere to hospital partners' policies and procedures with regards to various sources of information such as health records and databases.
- Maintain the confidentiality of patient files and study data.
- File and maintain a variety of documents such as source documentation, case report forms, and clinical records according to established regulations.

Supervision

- Provide direction to others in how to carry out work tasks.

Qualifications

- Bachelor’s degree in Nursing.
- Requires 4 years of relevant experience.
- Must be registered and maintain annual registration with the College of Nurses of Ontario as a Registered Nurse.

Effort

Physical Effort:

- A typical work day consists of greater than 3.5 hours of low physical effort for activities such as:
    - Intermittent periods of keyboarding to word process documents, enter data into databases and spreadsheets, and to update patient records.
- A typical work day consists of up to 3.5 hours of moderate physical effort for activities such as:
    - Standing to perform patient assessments.
    - Pipetting samples and administering medication through injections.
- Elements of high physical effort are not a regular feature of this job.

Mental Effort:

- A typical work day occasionally requires routine mental effort for activities such as:
    - Collecting routine information, word processing routine documents, and inputting data into databases and spreadsheets.
- A typical work day consists of up to 2 hours of moderate mental effort for activities such as:
    - Mediating with family members and caregivers who may be reluctant to have their family member involved in a study and educate them regarding the disease process and the benefits of clinical studies.
    - Liaising between the clinic centre and remote clinic sites and personnel.
    - Ensuring that the relevant research methodology is applied and all research material is handled in accordance with established protocols, policies, and procedures.
    - Conducting and processing study specific assessments of patients to determine suitability for projects and degree of disease acuity.
- A typical work day consists of greater than 3.5 hours of high mental effort for activities such as:
    - Participating in the development and authoring of research protocols.
    - Troubleshooting problems at all stages of study development and implementation.
    - Interviewing patients and assessing eligibility for participation in research studies.
    - Analyzing information to ensure the accuracy and appropriateness of patient management.
    - Analyzing patient responses and adverse events that may be experienced by a patient during the study
    - Applying specialized knowledge and scientific principles to review, critically appraise and interpret published literature.

Working Conditions

Physical Environment:

- Occasionally exposed to unpleasant odours when conducting patient assessments.
- Occasionally exposed to biological or repulsive substances when assessing patients.
- Frequently required to wear personal protective equipment such as gowns, gloves, and goggles when in contact with patients.

Psychological Environment:

- Occasionally interacts with individuals who may be rude or upset.
- Frequently handles multiple requests and simultaneous deadlines.

Health & Safety:

- Handles biological lab specimens including blood, urine, and mucous.
- Potential needlestick injury due to experimental procedures involving injections.
- Occasionally travels to others sites for meetings and to conduct patient assessments.

Job Description Rating Sheet

(For Positions in CAW Local 555, Unit 1)

JD #:	**JD00647**	Pay Grade:	**10**
JD Title:	**Clinical Research Nurse (I)**	Total Points:	**654**
Job Family:	**Research Coordinator**		

Factor	Subfactor	Level Rating	Points
Skill	1. Applied Reasoning and Analytical Skills	**5.0**	105
	2. Breadth of Knowledge	**3.0**	20
	3. Adaptation to Change/Updating of Learning	**2.5**	17
	4. Interpersonal Skill	**4.0**	54
	5. Education and Experience	**E3**	100
	6. Dexterity and Coordination	**3.0**	21
Effort	7. Physical Effort	**2.0**	11
	8. Mental Effort	**5.0**	100
Responsibility	9. Planning and Coordination	**4.0**	64
	10. Responsibility for Others	**2.0**	33
	11. Accountability for Decisions Actions Affecting People, Assets, and Information	**4.0**	93
Working Conditions	12. Physical Environment	**2.0**	10
	13. Psychological Environment	**2.0**	10
	14. Health and Safety	**2.0**	16