TITLE: 
Research Assistant – Level 2

ACCOUNTABILITY: Principal Investigator, Sub-Investigators, Project Leader-Clinical Research, Senior Clinical Research Coordinator

NATURE OF THE FUNCTION:
The Research Assistant - Level 2 is responsible for supporting the conduct of the clinical research study under close supervision by a senior member of the research team and the study investigator. The Research Assistant - Level 2 under the supervision of his/her immediate supervisor coordinates the clinical research activities as outlined in the study protocol and other research documents. The Research Assistant - Level 2 will be involved in the supervision of trainees and other staff, and is expected to show a high level of independence in carrying out their workload. This may include but is not limited to: 1) implementation of the research protocol and Standard Operating Procedures (SOPs), 2) coordinating the contract negotiation and submission to the research contracts office, 3) following regulatory requirements, 4) recruitment of research participants, 5) communication with sponsors and governmental authorities, 6) coordinating research ethics review and other regulatory requirements, 7) liaising with other collaborators, 8) data collection and management, 9) archiving data, 10) managing monitoring visits and submission of data, 11) conducting literature reviews, 12) performing basic data analysis, 13) contributing to the writing research reports and scientific articles, 14) contributing to the dissemination of findings (oral and poster presentations). Ultimately, Research Assistants – Level 2 are tasked with ensuring that the clinical research project(s) is efficiently carried out, with necessary safeguarding of research participants rights and well-being, and in compliance with the protocol and regulatory requirements that govern research involving human participants.

DUTIES AND RESPONSIBILITIES:

- Applies recruitment strategies and aids in the recruitment of research participants
- Ensures that research participants are provided with information and documentation relating to the research study
- Prepares, submits and follows-up on necessary regulatory and ethics documents
- Ensures or participates in the informed consent process and document
- Administers and ensures completion of structured questionnaires, interviews in person or at a distance, bedside observations, and chart reviews as defined by the protocol
- Coordinates and organizes study start-up and initiation process
- Coordinates patient visits as per protocol, reports deviations and violations as the case may be
- Organizes and participates in clinical team meetings
- Maintains required regulatory documentation and ensures confidentiality as per the legal and ethical requirements
DUTIES AND RESPONSIBILITIES (cont’d):

- Coordinates and manages adverse event notification to various entities
- Completion and management of Case Report Forms
- Data collection, entry, management, storage and long term archiving
- Performs descriptive and inferential statistical analyses and assists with qualitative coding
- Responds to queries and requests for information
- Participates in conferences (e.g., poster presentations)
- Prepares and submits publications
- Liaison between clinical research team and hospital departments
- Conducts other related tasks as assigned by supervisor
- The lists of duties and responsibilities outlined above are representative and not a complete and detailed list of tasks, which may be performed by an employee whose position has been matched to this generic job description.

JOB QUALIFICATIONS AND REQUIREMENTS:

- Minimally a Bachelors in Health sciences, Masters preferred, or related field with at least 2 years of experience
- Bilingual: French and English written and spoken
- Excellent computer skills including, Word, Excel, PowerPoint, and Outlook an asset
- Ability to perform statistical analyses with SPSS or SAS software (an asset)
- Demonstrated, excellent communication, organization and interpersonal skills
- Great commitment to accuracy of data and must be highly detailed oriented
- Ability to work independently, able to take initiative, and demonstrated team player capabilities
- Knowledge of research regulations (Health Canada, GCP, FDA) and applicable ethical standards (Tri-council policy guidelines)
- Outstanding ability to manage timelines and tight schedules