POSITION SUMMARY

QUEEN'S UNIVERSITY - GENERAL STAFF

POSITION TITLE: Study Coordinator
DEPARTMENT: NCIC Clinical Trials Group
POSITION NUMBER: 00501537
GRADE: 8 EFFECTIVE DATE: April 17 2014

JOB SUMMARY:
Work within a team based structure to coordinate and oversee national, international and cooperative oncology group, multi-centre, multi-modality clinical trials in cancer therapy, prevention and supportive care. Design, develop clinical trials protocols and data collection modules. Establish and maintain a coherent database. Work collaboratively with participating centres (cancer treatment centres) and trial committees (including investigators, clinical research associates, pharmacists), industry partners and others in an evolving international clinical trials environment. Promote an awareness and understanding of trial design, goals, and procedures in compliance with ICH- GCP and other relevant guidelines. Critical evaluation of incoming information, including medical data, for accuracy, relevance and prioritization. Orchestrate trial analyses leading to the dissemination of results and eventual publications.

KEY RESPONSIBILITIES:

- Apply an understanding of clinical trials methodology, data collection and analysis, and cancer biology, diagnosis and treatment in order to contribute to the design and development of multi-centre clinical trials in cancer therapy and supportive care. Research and write specific sections of protocols and trial specific grant applications. Develop familiarity with correlative study endpoints (including tumour banking, patient reported outcomes, economic analysis) and logistics to ensure successful completion of these aspects of clinical trials. Develop written materials for general education, trial specific training for participating sites, and contribute to abstracts, presentations and eventual publication of study results.

- Apply an understanding of current computer systems and applications in clinical trials conduct to coordinate the establishment, testing and maintenance of a coherent and consistent database for each assigned trial. Create and/or utilize templates to develop trial specific paper or electronic case report forms, including system-based, SAS and manual edit checks that will ensure accuracy of the clinical database. Coordinate the process of computerized data retrieval by interacting with the computing and biostatistics teams. Contribute to the development of the statistical analysis plan where appropriate, preparation of annual reports.

- Assess and interpret data and reconcile against medical supporting documentation on participants entered on assigned trials with particular emphasis on ensuring protocol compliance, monitoring toxicity and verifying patient response to treatment. Using

established metrics/reports, monitor all assigned trials for unexpected trends in patient accrual, eligibility, toxicity, response, deaths and patterns of practice which may compromise trial integrity. Query to ensure accurate reporting of complex endpoints, including response assessment, treatment modifications and adverse events. Stipulate and enforce documentation requirements, clarifying ambiguities and requesting missing or late data. Ensure compliance with relevant regulations including timely reporting of all serious adverse events and coordination/management/documentation of the investigational medicinal product supply.

- Provide guidance and support for study conduct to participating member centres, external committees (including investigators, clinical research associates, pharmacists), industry partners and others, as required. Utilize current technologies to actively promote trials to participating sites; conduct site training, including development and presentation of training materials. Act as a resource for site questions about study design, conduct and data capture. Interact with internal departments (information technology, audit and monitoring, ethics and requlatory, finance) to ensure timely and efficient trial conduct; participate on internal committees to advance/improve internal processes. Roles may also include membership on disease site committees and opportunities for contribution to the international clinical trial enterprise.

- Study Coordinators delegate work and ensure its completeness and accuracy to team members including research associates, clinical trials assistants, and students. Participates in the training and mentoring of new study coordinators and others.

REQUIRED QUALIFICATIONS:

- Master's degree in Health Sciences or equivalent combination of education and experience in a medical, research or pharmaceutical setting.

- Minimum of 2-3 years relevant experience in one or more of the following: clinical research, clinical trial methodology, oncology, health sciences or equivalent combination of education and experience.

SPECIAL SKILLS:

- Understanding of IT systems capabilities including evolving electronic data capture systems (e.g. Medidata Rave)
- Computer skills including WORD, Excel, Oracle, electronic data capture (e.g RAVE)
- Knowledge of statistics, data checking and SAS
- Excellent organizational skills
- Strong task oriented work ethic; work to tight deadlines
- Flexible with respect to ongoing evolution of work practices
- Attention to detail
- Superior communication skills both written and verbal

- Ability to work both independently and as a team member to liaise effectively in a professional and cooperative spirit with colleagues within the central office and at national and international study sites
- Proactive, consultative, collaborative
- Proven problem solving and analytical skills, and the ability to conceptualize, assimilate and evaluate information from multiple sources
- Manage stakeholder expectations
- Ability/enthusiasm to learn new skills
- Ability to prioritize competing demands
- Ability to critically and accurately review and interpret medical data
- Project management to monitor progress and ensure deliverables
- Working knowledge of French is an asset

DECISION MAKING:

- Make independent decisions in response to issues arising in trial development and ongoing management of active trials. These may include queries from cancer treatment centres and industry partners regarding interpretation of protocols, forms, patient eligibility and patient management.
- Determine when, how and to whom to report serious adverse events.
- Independent, ongoing assessment of workload priorities is essential to integrate the overall organization, day-to-day administration, medical review of data and analyses of many trials.

FOR RESEARCH POSITIONS ONLY:

	YES	NO
1. Is this position technical in nature in a lab or lab-related area?	☐	x
2. Does this position support a research project?	x	☐
If yes, indicate name of the project: Multiple trials of the NCIC Clinical Trials Group		
3. Does this position report directly to a Principal Investigator (PI)?	☐	x
If yes, indicate name of the PI:		

SIGNATURES:

	Date
Incumbent	
Manager	
Department Head/Director or Designate	