POSITION SUMMARY

QUEEN'S UNIVERSITY - GENERAL STAFF

POSITION TITLE:	Monitor/Auditor	
DEPARTMENT:	Canadian Cancer Trials Group	
POSITION NUMBER:	00125702	
GRADE:	8	EFFECTIVE DATE: March 28, 2017

JOB SUMMARY:

Under the supervision of the Compliance Group (CG) Team Leader, the incumbent will conduct quality control and assurance activities for Canadian Cancer Trials Group (CCTG) clinical trials in North America providing support to both the monitoring and audit programs as required.

The Monitor/Auditor will also participate in other compliance activities including, but not limited to, involvement with the Centre Performance Index (CPI) and Online Information Organization Network (ONION), and participation on committees and training programs critical to compliance assurance. The incumbent will also participate in central office data review, assessment, and querying procedures as needed.

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 oversight and review of multi-centre clinical trials in cancer therapy and supportive care.
- Coordinate and participate in quality control and assurance activities with participating member centres (cancer treatment centres), vendors, and collaborators, as well as internal trial teams, in order to ensure compliance.
- Interpret findings and identify issues such as non-compliance or scientific misconduct and notify CCTG personnel as needed. Ensure appropriate corrective action is undertaken for any identified deficiencies.
- Coordinate and participate in external audits and/or regulatory inspections in support of the overall quality control and assurance program of CCTG.
- Apply an understanding of the current computer systems and applications in clinical trials conduct to effectively conduct compliance activities (e.g. EDC Medidata Rave). Provide education to participating member centres during on-site reviews and liaise internally to ensure trial standards.
- Promote awareness and understanding of Good Clinical Practice and other appropriate compliance procedures and guidelines. To act as a representative of CCTG in interactions with member centres while conducting on site monitoring visits.
- Delegate work to AMG Assistants and ensure its completeness and accuracy. Participate in the training and mentoring of new monitors/auditors 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, quality assurance, monitoring. Or equivalent combination of education and experience.

SPECIAL SKILLS:

- Excellent organizational skills.
- Attention to detail.
- Superior communication skills both written and verbal.
- Ability to work independently and liaise effectively in a cooperative spirit with colleagues both within the central office and across the country.
- Ability to prioritize competing demands.
- Ability/enthusiasm to learn new skills.
- Proactive, consultative, and collaborative.
- Proven problem solving and analytical skills.
- Understanding of IT systems capabilities including evolving electronic data capture systems (e.g. Medidata Rave).
- Computer skills including WORD, Excel, Oracle.
- Working knowledge of French is an asset.
- Ability to travel in North America approximately 60% time.

DECISION MAKING:

- Interpret findings and identify issues such as non-compliance or scientific misconduct and notify CCTG personnel as needed.
- Determine and ensure implementation of appropriate corrective action required to resolve any identified deficiencies.
- Independent, ongoing assessment of workload priorities is essential to integrate the overall organization, day-to-day administration, and medical review of data and analyses of many trials.
- Participate in ongoing review of CCTG SOPs to ensure optimal methods to assess compliance are in place; assure consistency across Compliance.
- Oversees, delegates and assesses the quality of work of the AMG Assistants, and recommends need for formal training or development plans and identifies possible staff performance and/or disciplinary issues to Team Leader.

RESEARCH ASSESSMENT QUESTIONS: YES NO
(must be completed)

1. Is this position technical in nature in a teaching or research lab or lab-related area? ☐ ☒
2. Does this position support a research project? ☒ ☐
   If yes, indicate name of the project:
3. Does this position report directly to a Principal Investigator (PI)? ☐ ☒
   If yes, indicate name of the PI:

SIGNATURES:

	Date
Incumbent	
Manager	
Department Head/Director or Designate	