WOMEN'S COLLEGE HOSPITAL
Health care for women | REVOLUTIONIZED

EMPLOYMENT OPPORTUNITY

Women's College Hospital is the first and only independent, academic, ambulatory care hospital in Ontario with a primary focus on the health of women. If you're ready to be part of the future of healthcare, then you will want to join an institution in which the possibilities for creative innovation, breakthroughs in new thinking and groundbreaking work in academic ambulatory medicine are limitless. Women's College Hospital is committed to patient safety as a key professional value and an essential component of daily practice.

An exciting **regular full-time** opportunity as a **Research Quality Assurance Coordinator (Competition #83.18)** exists reporting to the Director, Research Operations.

The Coordinator is an integral team member supporting research and clinical trial quality and excellence. Specifically, the Coordinator is responsible for the coordination and facilitation of activities aimed at enhancing and maintaining quality assurance and regulatory compliance. The incumbent must be willing to work collaboratively and cooperatively in a challenging and dynamic environment and will be responsible for the activities outlined below.

Summary of Duties, but not limited to:

- Facilitate the intake, tracking and review of all clinical trials
- Assess risk of each clinical trial using WCH's established framework
- Work with clinical research teams to develop and implement a risk-based monitoring plan for WCH sponsored trials, consistent with relevant Health Canada regulations
- Validate that the reported trial data are accurate, complete, and verifiable from source documents
- Work with investigators to ensure that the trial is conducted in compliance with the approved protocol, Good Clinical Practice (GCP) and applicable regulatory requirements
- Support appropriate use of organizational-level Standard Operating Procedures (SOPs) by investigators
- Monitor patient eligibility, including reviewing informed consent form completion, confirm PHIPA compliance and verify patient eligibility
- Monitor protocol implementation and identify protocol violations/deviations
- Monitor data collection and adverse event reporting including, perform source and case report forms (CRF)/eCRF data review, retrieve clinical data (i.e., CRFs), monitor adverse event reporting, handle query resolutions
- Examine reasons for screen failure or withdrawal, perform drug and/or device accountability for WCH sponsored trials and maintain complete regulatory documents and clinical study performance metrics for WCH sponsored trials
- Support study close out by performing final source documentation and CRF/eCRF data review; reconcile regulatory documents; finalize adverse event documentation, patient disposition and query resolution; and retrieve the remaining completed CRFs and resolved queries for WCH sponsored trials
- Complete a monitoring visit report after each site visit and identify areas of noncompliance
- Coordinate requests for regulatory audits
- Support monitoring visits for non-WCH sponsored trials
- Support the development and monitoring of SOPs for clinical trials at WCH
- Identify needs and deliver ongoing orientation, education and training to scientists, researchers and staff involved in clinical trials and research
- Support quality assurance for all research projects at WCH according to established framework

As a role model and champion you will work to identify and integrate safe, best practices into daily activities to foster the delivery of safe and exemplary care.

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The responsibilities described above are representative and are not to be construed as all-inclusive.

Qualifications/Skills:

- Post-Secondary education in a Health Science field of study is required, Bachelor of Science (BSc.) or Nursing preferred
- Recognized certification in clinical research (ACRP or SOCRA)
- Experience in conducting or monitoring clinical trials
- Advanced knowledge of the current clinical trials regulatory environment, including drug, natural health products and medical devices
    - Health Canada regulations
    - FDA Code of Federal Regulations
    - FDA Audit procedures
    - Tri-Council Policy
- Excellent knowledge of International Council for Harmonisation Good Clinical Practice
- Excellent organizational and administrative skills with attention to detail
- Ability to work independently with a high degree of initiative, discretion and tact
- Strong time management skills as well as experience prioritizing and working in a dynamic environment
- Proficiency in Microsoft Office including Outlook, Word, Excel, and Powerpoint
- Experience completing ethics/regulatory submissions
- Proficient in MS Windows environment (Word, Excel, Power Point)
- Demonstrates excellence interpersonal, verbal, and written communication skills
- Innovative and willing to learn
- Demonstrates individual leadership skills and autonomous critical thinking ability
- Experience with Adobe Acrobat
- Good attendance record is required
- Professional behavior and communication that meets the standards of the professional regulatory college or association, as applicable, and the standards of Women's College Hospital.
- This position plays a critical role in acting as an advocate for safety and will demonstrate principles, practices and processes that will optimize a safe environment for all.

POSTING DATE: Wednesday April 4, 2018
CLOSTING DATE: Wednesday April 18, 2018

Please forward resumes via email to HR@wchospital.ca with your name and the competition number in the subject line. (Example: Jane Smith, 1.16)

We thank you for your interest, however, only qualified applicants who are selected to be interviewed will be contacted.

Women's College Hospital is a fully affiliated teaching hospital of the University of Toronto and is committed to fairness and equity in employment and our recruitment and selection practices. We encourage applications from Aboriginal peoples, people with disabilities, members of sexual minority groups, members of racialized groups, women and any others who may contribute to the further diversification of our Hospital community. Accommodation will be provided in all parts of the hiring process as required under our Access for People with Disabilities policy. Applicants need to make their requirements known in advance.