Job Posting

Research Coordinator-Monitor, C^{17} Council, Pediatric Hematology/Oncology

Status: 1.0 FTE – Regular Full Time position
City/Town: Remote, eastern Canada
Date Closed: 10Dec2024 - Consideration of applicants may start prior to this date
Position Starts: As soon as possible
Hours of Work: Days, standard 8 hours / day Monday – Friday, 8:00 am – 4:00 pm – flexible time based on work/location/personal preference, occasional travel/weekend days
Salary: Commensurate with experience

C^{17} Council is a network that links the 16 Pediatric Hematology/Oncology and Bone Marrow Transplant programs across Canada for research, regulatory compliance, education, human resources and advocacy. Our work includes international collaborations, working with researchers, REBs, institutions and academic cooperative groups, and collaborating with patient and family advocates. Our office has transitioned to a fully remote work-from-home model, with some office support in Edmonton, Alberta. To be eligible for this position, candidates must reside in eastern Canada to conduct some on-site regulatory oversight and monitoring activities.

Responsibilities/Duties:

- The Research Coordinator will report to the C^{17} Executive Director and Regulatory Manager
- Work closely with the C^{17} office, centres across Canada, and the C^{17} executive to fulfill the research, regulatory and education mandate of C^{17}
- Monitoring of Canadian clinical trial sites based on Health Canada regulations for multicentre clinical trials being conducted through academic cooperative groups
- Conducting regular remote and onsite visits, primarily in Ontario and Quebec, to monitor compliance with regulatory requirements and oversee corrective actions
- Additional support to other portfolios (based on education and experience) may include support of:
    - National and provincial REB initiatives and applications
    - Precision medicine programs
    - Managing single patient studies
    - Operationalizing remote access and decentralized clinical trial options
    - Assisting with Clinical Trial Applications and amendments to Health Canada for review and approval
    - Respond to queries from Health Canada
    - Working with other organizations to run pediatric initiatives
- Review informed consent forms for compliance with sponsor requirements
- Collaborate with site staff to evaluate site performance, identify potential issues, and provide recommendations for improvement
- Document findings, site observations and recommendations in regular monitoring visit reports
- Maintain files and databases; document information promptly and precisely; develop SOPs and guidance
- Liaise between institutions, investigators, clinical trial sites, sponsors, companies, and Health Canada
- Assist with C^{17} operations and office responsibilities

Qualifications:

- Bachelor's degree in a research or health-related field; 3 years clinical research experience; exceptions can be made if experience or track record indicates capability and suitability. Experience in oncology or hematology preferred
- Previous clinical trial monitoring experience would be an asset
- Knowledge of Canadian (Division 5, ICH GCP) and US (NIH, FDA) regulations
- Familiarity with Microsoft Office software, clinical trial databases
- Excellent organizational, communication, problem-solving and interpersonal skills, high degree of accuracy and attention to detail

- Able to take initiative and work in a team environment or independently; capacity to be flexible, work well under pressure and able to meet deadlines
- Able to work efficiently, in a professional, confidential and ethical manner in accordance with industry policies/procedures
- Ability to travel within Canada and the US.

To apply: Please email your resume directly to Kathy Brodeur-Robb at kathy.brodeur-robb@c17.ca