



Job Description

Department	Clinical Operations
Designation	Part Time Clinical Research Coordinator I
Location	Mississauga, Ontario
Basic qualification required	<ol style="list-style-type: none"> 1. Sc., post-secondary diploma in scientific, healthcare or pharmaceutical field, or equivalent. 2. Minimum 3 years' experience in a clinical research environment preferably including BE and Ph 1– IV studies, EEC is desirable 3. Strong analytical and problem-solving skills 4. Demonstrated superior leadership skills 5. Excellent organizational skills, detail oriented, efficient and able to multi-task and prioritize effectively 6. Excellent interpersonal skills 7. Strong written and verbal communication skills 8. Good trouble-shooting and decision-making skills, able to escalate response to situations when relevant 9. Proven solid project planning/coordination/management skills
Experience	2-3 Years
Brief JD	<ol style="list-style-type: none"> 1. Independently Lead the overall coordination and management of clinical studies for BE and Phase 1-4 including but not limited to: 2. Recruitment, screening, and coordination of patient visits as per study protocols 3. Execution of all aspects of study visits as experience and training allow 4. Perform clinical and study procedures as per study protocols, ensuring minimal deviations and proper tracking and reporting when deviations occur 5. Interact with Principal Investigator, sponsor, manager and Scientific Director and other study coordinators to ensure all aspects of protocols and study requirements are understood 6. Design, implementation and coordination of all aspects of data collection, source documentation and CRF transcription as per protocol, SOPs and ICH/GCP guidelines 7. Data entry 8. Participate in development and execution of Quality Control processes 9. Prepare for and support QA audits and sponsor monitoring visits 10. Study drug management 11. Lab Sample processing, labelling, storage, shipment, documentation and record keeping 12. IRBs interactions 13. Site Regulatory Documentation collection and management 14. Archiving 15. Work with study managers and other members of the study teams to ensure study performance meets or exceeds client expectations 16. Participate in Operational kick-off meetings and regular study update meetings



17. Ensure study subjects are having the best possible experience while participating in studies conducted at Cliantha Research Limited.
18. Participate in development of department SOPs, Equipment Binders, templates
19. Procurement of equipment and supplies as required
20. Calibration and maintenance of equipment per SOPs; Maintain appropriate logbooks
21. Participate in training of staff as experience and qualifications permit
22. Participate in Environmental Chamber validations and maintenance; write validation protocols and reports, conduct validation experiments, maintain appropriate logbooks
23. Assist in all aspects of company start up activities as required
24. Uphold the company mission statement and conduct yourself at all times in a respectful and business-like manner. Be a positive role model for all staff and interact with colleagues in a collaborative way
25. Assist in set up and maintenance of laboratory and EMS system
26. Execution of other duties as may be required