

Clinical Research Coordinator

The Canadian Centre for Psychedelic Science is a Canadian-based consulting firm dedicated to the advancement of psychedelic science and therapeutics.

We are looking for an experienced Toronto based Clinical Research Coordinator (CRC) to work directly with the Principle Investigator (PI) and Research Director on assigned clinical research trials, ensuring all study activities are properly executed, meeting study protocol, BPSI SOPs, ICH-GCPs and regulatory requirements. Must be available to come to the clinic in person on weekends.

Responsibilities:

- Coordinate, monitor and supervise all study activities to ensure proper execution of assigned clinical research trials and to ensure that study protocols, BPSI SOPs, ICH-GCPs, and regulatory requirements are met.
- Manage and maintain a controlled records management system for electronic trial master file and related clinical trials.
- Prepare and maintain administrative logs and trackers, including but not limited to Regulatory Documents Collection tracker, eTMF tracker, Health Canada submission tracker, Central IRB Submission tracker, Site Shipments tracker, study visits, etc.
- Liaise with PI and Research Director, organizing study visits for participants.
- Facilitate the collection, filing and tracking of study visits, surveys documents and other related study documents, including monitoring reports.
- Prepare study and site level Regulatory Ethics submissions and attain Regulatory Ethics approval, including but not limited to Initial Ethics submissions, Renewal submissions, SAE Reports submission, Protocol Deviations submission, Study Advertisements submission, etc.
- Review and prepare site specific ICFs for ethics submissions.
- Prepare regulatory packages and study start-up binders and tools for clinical trial sites and coordinate shipment of trial materials, trial equipment and supplies to site as necessary.
- Tracking monthly and quarterly clinical equipment and supplies inventory.
- Coordinate site training as applicable (i.e. Protocol related training, technical training, eCRF training, SIV etc.).
- Plan, implement, and coordinate all aspects of data collection and source documentation as per company policy and industry guidelines. Responsible for data entry using study databases.
- Prepare and distribute status update reports showing study progress.
- Review, identify, and escalate adverse events to PI.
- Coordinate subject visit schedules as per study protocol, executing all aspects of study visits (i.e. assessments, documentation of adverse events and medications, administer questionnaires, sample collection, and other related responsibilities as required).

Qualifications:

- Completed post-secondary degree in a science or healthcare related discipline, or equivalent work experience
- 3+ years work experience as a Clinical Research Coordinator or similar role in a CRO (preferably in conducting Phase I/II clinical trials)
- 2+ years experience in overseeing a research team
- Certification in clinical research (i.e. SoCRA, ACRP) is an asset

- In-depth knowledge of the clinical trial process, from study start up to close out
- Advanced knowledge of ICH guidelines and GCP including basic understanding of regulatory requirements
- Strong understanding of the regulatory process and establishing and maintaining clinical study source documents
- Advanced use of Microsoft Office Word, Excel and PowerPoint
- Excellent problem solving, communication, multitasking and interpersonal skills
- Ability to work independently, in a fast-paced environment with a high degree of organization