

Job Description: Research Site Start-Up Specialist:

The World Health Research (WHR) Site Start-Up Specialist supports the study team (project manager, project coordinator, and administrative assistant), focused on overseeing and coordinating the initial phases of clinical trial operations, including site identification, feasibility assessments, regulatory submissions, and study initiation activities. The ideal candidate will possess strong organizational skills, attention to detail, and a collaborative mindset.

- 1. The ideal candidate has knowledge of clinical research principles, regulatory guidelines, and industry best practices.
- 2. The position requires the ability to work independently as well as collaboratively with cross-functional teams to ensure timely and accurate completion of tasks.

Key Responsibilities:

- Collaborate with internal and external stakeholders to manage site identification, invitation, selection, and feasibility processes.
- Prepare, review, and submit regulatory documents to ensure compliance with local, regional, and international guidelines.
- Coordinate with clinical sites to facilitate contracts, budgets, and essential document collection.
- Monitor and communicate progress of study start-up activities, identifying and resolving any issues or delays.
- Ensure adherence to timelines, budgets, and regulatory requirements for study start-up activities.
- Maintain and update databases, trackers, and documentation related to study start-up processes.
- Develop regular newsletters and update the study websites.
- Serve as the primary point of contact for study start-up matters for internal and external stakeholders.

Qualifications and Experience:

- 1. Bachelor's degree in health sciences or a related field.
- 2. Recent (2 years) experience with clinical trials and/or large research studies, particularly in study start-up activities.
- 3. In-depth knowledge of ICH-GCP, Health Canada Division 5, and clinical trial guidelines and processes.

- 4. Strong communication, negotiation, and problem-solving skills.
- 5. Proficiency in Microsoft Office Suite.
- 6. Demonstrated strong initiative and drive and the ability to be self directed.

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Please send Resume and Cover Letter to human-resources@worldhealthresearch.ca