**Vishwambari, MBBS, CRP**

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**Summary of Qualifications**

* Accomplished Clinical Research Professional (CRP) and medical doctor (MBBS) with extensive research experience in hospital and clinical setting of 2 years as a research assistant
* Specialized in International, Canadian, and US Clinical Research laws and regulations
* Proficient in ICH-GCP (E6(R2), E2, E8), FDA 21, CFR 312, 56, 50, 54, Form 1572/QIU, IND/CTA and NDA/NDS, TCPS ethical considerations, process of REB approval
* Highly skilled in ensuring the quality of clinical trial projects by verifying materials inventory and data integrity with source documents
* Skilled in Electronic Data Capture (EDC), Clinical Trial Management Software (CTMS), and SSPS statistical software
* Trained on drafting appropriate intervention plans to monitoring plans and visit reports
* Outstanding written communication skills with high attention to detail

**Professional Experience**

**Clinical Research Assistant Intern** March 2022- Present

*Access Clinical Research, Montreal, Quebec, Canada*

* Researcher working on clinical trials in oncology
* Prepare presentations for the clinical trials
* Update and ensure the quality of presentations and documents according to recent information
* Monitor and track clinical trends, patterns, and practices
* Data capture and analysis of various methodologies, drugs, and procedures used in oncology
* Review research study requirements and draft evaluation reports

**Clinical Research Graduate** August 2021 to April 2022

*International Clinical Research Academy, Montreal, Canada*

* Traced clinical trials, protocol synopsis, feasibility questionnaires, SOP checklists, information brochure (IB), informed consent design
* Executed study start-up (SSU) activities like reviewing of informed consent form, information collection for protocol compliance
* Integrated medical and periodic reports in addition to reviewing and submitting case report forms
* Verified reporting on safety, adverse effects (AE), and serious side effects (SAE)
* prepared support for close out visits of centers upon completion of study trials

**Clinical/Research Assistant** July 2012- Feb 2019 *Veda Holistic Healthcare, Hyderabad, India*

* Administered Mistletoe Therapy (Helixor) to cancer patients as an alternate therapy along with the conventional treatment
* **Recorded and reported outcomes of Mistletoe Therapy on patient immunity and tolerability of conventional drugs**
* Maintained records of drug supply, dispense, storage, and dosage
* Supervised patient enrollment log, source documentation, and case report forms
* Served as immediate point of contact for information and queries for patients and their families
* Presented effects of Mistletoe (Helixor) on early-stage Breast cancer along with conventional treatment
* Compiled research data to be used for multicenter research trials
* Trained site staff on therapeutic areas, protocol requirements and prepared interview questions
* Ensured strict compliance to study relevant standard operating procedures (SOPs)
* Analyzed qualitative data stemming from various research projects

**Skills & Specialties**

* Tech Savvy Skills: EDC/CTMS, SPSS, Microsoft Word, Excel, Power Point, Outlook, Adobe Acrobat, Datatrack
* Experienced in working with EPIC, MedTech, and OSCAR
* Implement advance Electronic Informed Consent solutions (eICF), transfer imaging data online
* Adaptive thinking depicted during the COVID pandemic
* Strong communicator able to engage and influence diverse group of patients
* Developed superior conflict resolution instincts with experience
* Talent maximiser, team player
* Self-motivated and lifelong learner
* Authentic and consistent in hard work
* Coached colleagues, patients, vendors especially about COVID and importance of vaccination
* Exemplary troubleshooting skills prominently demonstrated during the management of COVID patients
* Enthusiastic about learning and excelling with the team
* Versatile written and oral communication skills.
* Excellent organizational and time management skills
* Volunteered for government initiatives to prevent the spread of COVID-19
* Facilitated COVID-19 test sample collection, preservation and transport at government hospitals
* Ability to work effectively to ensure projects are delivered in accordance with the project specifications, budget and agreed schedule

**Education**

**Clinical Research Professional (CRA+CRC)**, Certificate April 2022

International Clinical Research Academy, Montreal,

* Systematic Approach to Effectively Manage Multi-Center Trials,
* IND & CTA, IRB, SSU, TMF, CRF, AE/SAE, SDV, SOPs, DM
* Initiation, Interim & Close-out Visits, Reporting & Retention.
* FDA & TPD Audits, Fraud & Misconduct, Medical devices

**MBBS**  July 2010

Kursk State Medical University (Russia)

**Certifications**

Good Clinical Practice (GCP)- Canada CITI Program Certificate

Responsible Conduct of Research CITI Program Certificate

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans Certificate