CLINICAL TRIAL COORDINATOR

(1-year contract; Payclass 09)

Child Development Research Laboratory

Faculty of Health Sciences

The Child Development Research Laboratory (CDRL) invites applications from suitably qualified candidates to fill a Clinical Trial Coordinator post on a 1-year full-time contract. The CDRL in the Division of Biomedical Engineering of the Department of Human Biology studies the effects of prenatal exposure to toxins on infant and child development. We are seeking an experienced, dynamic individual to oversee clinical trial operations in a double-blind, randomized controlled trial of a nutritional supplement in pregnant women that is being conducted in the Stellenbosch Health sub-district. The incumbent will be based at our CDRL office in Stellenbosch, and will attend other sites in the Stellenbosch area as required. Although the contract will initially be for 1 year, there is potential of renewal for a further 3-4 years.

Requirements:

- NQF 7 qualification in Nursing.
- 3 to 5 years' experience working as a clinical trial coordinator (e.g., knowledge of trials, quality control, development of SOPs)
- Excellent communication and interpersonal skills
- Strong decision-making skills
- Administrative, management & data entry experience
- Excellent knowledge of Good Clinical Practice (GCP) procedures
- SANC registration
- Fluency in English and Afrikaans
- Driver's license and access to personal car

Advantageous:

- Experience working in obstetrics/midwifery and/or paediatrics (clinical or research work)
- Experience working in public hospital setting

Responsibilities:

Ensuring compliance with regulatory requirements, GCP and Standard Operating Procedures (SOPs), you will work with a diverse clinical research team to help ensure the project is delivered within budget and on time, including:

- Maintaining effective and ongoing communication among the research participants, research staff and PIs during the study, e.g., ensuring any problems that are identified in the study are immediately brought to the attention of the PIs, sub-investigators and medical officer.
- Ensuring that the clinical research and activities are performed in accordance with the approved protocols, including reporting and recording protocol specific Serious Adverse Events (SAEs).
- Assisting with the performance of significant trial related duties in accordance with Good Clinical Practice (GCP) standards.
- Prepare and submit six monthly reports for continuing review to SAHPRA and annually to HRECs
- Follow-up of outstanding approvals from IRBs. Prepare and submit annual renewal applications to IRB.
- Keep binders for all regulatory, safety, and study-related documents and correspondence.
- Assist study PIs with various management tasks
- Partake in regular conference calls with the PIs and file all documentation of all communication, including minutes of conference calls/meetings.
- Provide feedback on questions and queries concerning the site or study specific issues.
- Address problems, issues that come from the community clinics.
- Assist with appointing new staff
- Assist the study team in ensuring the trial runs smoothly
- Responsible for daily study practices and management of the study from an administrative perspective, including financial management and reporting.
- Completing detailed study documentation and maintaining study files, regulatory binders, all study specific source documentation and other materials in accordance with the requirements of the sponsor and SAHPRA.
- Preparation for FDA/SAHPRA inspections and Audits, as well as assistance during the inspections and audits.
- Co-ordinate the logistics with various departments/entities (pharmacy, laboratory, courier company, UCT research finance, etc.)
- Identify and order all supplies (e.g., laboratory kits) needed for the study and ensure that they are available for the execution of the study.
- Schedule participant study visits, and coordinate home visits and staff work schedules.
- Telephonic contact with patients.
- Designing source documentation according to the study protocol and CRF and/or e-CRF.
- Oversee and audit data collection/completion.
- Assist medical staff with informed consent procedures, including explanation of research project.
- Oversee organization of biologic samples and processing of specimens and results via a commercial laboratory.

The annual cost of employment, including benefits is between R436 624 and R516 794.

To apply, please e-mail the below documents in a **single pdf file** to ernesta.meintjes@gmail.com

- UCT Application Form (download at http://forms.uct.ac.za/hr201.doc)
- Letter of motivation that speaks to the specific requirements of the position
- Curriculum vitae (CV)
- Proof of SANC registration and current South African Good Clinical Practice (GCP) certificate

Please ensure the title and reference number are indicated in the subject line.
An application which does not comply with the above requirements will be regarded as incomplete.
Only shortlisted candidates will be contacted and may be required to undergo an assessment.

Reference number: E22804 **Closing date:** 05 September 2022

"UCT is committed to the pursuit of excellence, diversity and redress in achieving its equity targets. Our Employment Equity Policy is available at http://www.uct.ac.za/downloads/uct.ac.za/about/policies/eepolicy.pdf. For this post we seek particularly to attract black South African (African/ Coloured/Indian) candidates and people with disabilities."

UCT reserves the right not to appoint.