TRIAL MANAGER
PARTICULARS OF APPOINTMENT

NIHR Global Health Research Unit on the prevention and management of stillbirths and neonatal deaths in Sub-Saharan Africa and South Asia.

Vacancy Ref: CUHAS/SB2/2021/04

POST: Trial Manager

Salary: Trial manager - SB2 package

Hours: Full-time

Duration of Contact: Fixed-term (48 months) January 2022- December 2025

Location: Manyara, Tanzania

Responsible to: Dr Rose Laisser (Tanzania lead) and Professor Dame Tina Lavender (UK lead). **Reports to:** Dr Paschal Mdoe (Manyara Tanzania) and Global Health Trail Unit (GHTU), Liverpool School of Tropical Medicine (LSTM) UK.

Number of Posts: 1 (One)

Enquiries about the vacancy, shortlisting or interviews:
The Administrator CUHAS -SB2 study
P O Box 1464
Mwanza, Tanzania
E-mail: vc@bugando.ac.tz *copy to* nkuba@bugando.ac.tz
Tel No. + 255 757 23 12 04

Role/Purpose/Summary. This Trial Manager Post will be a full-time role, employed by the Catholic University of Health Sciences (CUHAS), based at the Haydom Lutheran Hospital in Manyara, Tanzania.

The post holder will undertake a key role in planning, co-ordinating and delivering a cluster randomised controlled trial in Manyara region. They will be expected to deliver high quality research whilst maintaining excellent standards and practice.

Scope /Background. The trail manager will be part of the NIHR Global Health Research Unit (GHRU) on the Prevention and Management of Stillbirths and Neonatal Deaths in Sub-Saharan Africa and South Asia, led from the Centre for Childbirth, Women's and Newborn Health at Liverpool School of Tropical Medicine UK, which is an established equitable multidisciplinary partnership between Africa, Asia and UK-based researchers. Our goal is to end preventable stillbirths and newborn deaths, ensure adequate support for parents and families whose baby dies and reduce associated stigma. We aim to develop, test and implement sustainable and cost-

effective solutions to strengthen maternity and newborn care, reducing mortality and morbidity through high-quality, respectful and compassionate maternity and newborn care. Activities cover the entire spectrum of maternal and newborn health from preconception to post/neonatal care, with a strong focus on meaningful community and stakeholder partnerships. We co-produce research with women, families, front-line health workers and policy makers. ***The institutional partner in Tanzania for the delivery of the Unit research programme is the Catholic University of Health Sciences (CUHAS) in Mwanza under the leadership of Dr Rose Laisser, Senior Lecturer in Midwifery and Women's Health. The position will be located at Haydom Lutheran Hospital in Manyara alongside the research team for this workstream.***

As a trial manger, you would be working on a workstream aimed at improving antenatal care. Specifically, you will support testing of the hypothesis: ***Introduction of the Pregnancy and Newborn Diagnostic Assessment (PANDA) e-health system, alongside respectful care training will increase the number of antenatal contacts between woman and health-provider and reduce episodes of severe maternal/neonatal morbidity and mortality in Tanzania.*** You will have a key role in delivering a robust clinical trial, within a GCP envelope, and providing local researchers with the necessary tools/skills to conduct the research in a pragmatic but efficient manner.

The post holder will demonstrate enthusiasm, innovation and leadership when faced with challenges and will provide tactical and operational management skills in the planning and execution of the research.

They will work closely and in collaboration with the Trial Manager at the GHTU in LSTM, Workstream Lead, Country Lead, Principal Investigators, Data Managers, Statisticians, clinicians, and other relevant stakeholders. The post holder will be based in Haydom Lutheran Hospital, Manyara, but would be expected to travel within the region and to Mwanza.

ROLE SPECIFIC RESPONSIBILITIES

Key Responsibilities	Key actions
1. Trial Management	• To be responsible for the overall efficient day-to-day management of a clinical trial including obtaining all relevant approvals, budget management, site set up and recruitment, continued support through follow-up and close down procedures. • To develop the procedures to ensure adherence to regulatory and ethical requirements as well as trial protocols and administrative requirements.

	• To ensure full and open communications with all stakeholders in the trial to so that full approvals are met, delegation of duties is appropriate, study intervention is managed both internally and externally and the 'green light' process for site recruitment is effectively managed. • To co-ordinate the preparation and publication of data, reports and information, ensuring that they meet contractual and ethical requirements. • To liaise with the Trial Steering Committee and Independent Data Safety and Monitoring Committee with a particular view on compliance with Research Governance, Good Clinical Practice, Data Protection and Ethical Requirements • To plan and provide logistical support for study meetings • To produce and maintain the Trial Master File (TMF) to GCP standards • Track progress at each site and take appropriate action to ensure good recruitment, compliance with the protocol and the quality and timeliness of the data collection. • Working with in-country staff develop and implement strategies to monitor risk and address any practical difficulties reported by sites.
2. Trial support	• To provide general support to the Workstream Lead and Country Lead to ensure that the trial is progressing as planned, producing meaningful outputs, and to predict and plan any changes that warrant requests to protocol amendments • To work closely with the data manager to ensure data is received promptly from the sites • To work closely with the trial statisticians to ensure data queries are resolved in a timely manner • To work with the project team on the development of all documentation, with responsibility for the production of the Site Investigator Files, as part of the TMF • To contribute to the trial's public profile through newsletters, website administration and mailings to collaborating sites • Arrange meetings, teleconferences and video conferences relating to the project. • Prepare minutes and notes of meetings to maintain accurate logs of information for auditing and evaluation purposes and to distribute same in accordance with funder requirements.

	• Assist the Workstream Lead and Country Lead in arranging national and international meetings • Assist in updating the protocol, study materials, training packages for collaborating sites and trial manuals, and prepare trial specific instructions as required • Assist with the planning and delivery of trial specific training programmes to staff at participating sites
3. Collaboration with LSTM GHTU	• Support Authorship of trial specific SOPs and documentation. • Maintain accounts and preparation of required reports in conjunction with the LSTM Trial Manager. • Respond daily to queries from colleagues, collaborators and other stakeholders • Prioritise workload and delegate tasks (where appropriate) in order to achieve pre specified goals. • Implement effective communication strategies with stakeholders encompassing novel, pragmatic and diplomatic approaches. • Provide support and guidance to investigators, researchers, and junior members of staff in regards to research governance, trial management and queries relating to day-to-day operation of clinical trials. • To engage with external stakeholders to promote the research • Contribute towards social media relating to the study
3. Management/ Supervision	• Recruitment, training, appraisal and supervision of trial team members including Research Assistants and Data Manager
4. General	• To undertake any other tasks deemed appropriate for the role which are deemed necessary by the Workstream Lead • Promote equality of opportunity and inclusive practice in all aspects of work undertaken • Act in a manner that safeguards children and/or vulnerable adults as applicable to the role
5. Clinical Trial Manager Requirements:	• A holder of an MD/B.ScN MUST be registered by respective Council/Boards • 2+ years of work experience in related field. • Outstanding communication skills, both verbal and written. • Proficient with Microsoft Office Word and Excel

APPLICATIONS

- All applicants have to be Citizens of Tanzania.
- Application must be handwritten or typed in English.
- All application letters must be accompanied with detailed and current Curriculum Vitae, all relevant certificates and full transcripts.
- Names and valid addresses (and phone numbers or emails) of 3 credible referees must be provided.
- The deadline is **Monday 15th November, 2021** at **03:30.**
- Applications must be addressed and sent to:

VICE CHANCELLOR,
CATHOLIC UNIVERSITY OF HEALTH AND ALLIED SCIENCES (CUHAS)
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MWANZA,
TANZANIA.
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