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COLLEGE OF HEALTH SCIENCES
SCHOOL OF PUBLIC HEALTH
Office of the Dean

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

JOB DESCRIPTION

POST: Trial Manager

CONTRACT: Fixed term for 1 year [Renewal up to 2.5 years]

REFERENCE NO: NIHR01/03/TM

REPORTS TO: Country Principal Investigator, (MAK) and Global Health Trials Unit (GHTU), LSTM

ROLE PURPOSE/SUMMARY: This Trial Manager post will be a full-time role, employed by Makerere University School of Public Health, based in Kampala.

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

SCOPE/BACKGROUND: You 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. Using a whole systems approach, we work across high burden settings in India, Kenya, Malawi, Pakistan, Tanzania, Uganda, Zambia and Zimbabwe. 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 Uganda for the delivery of the Unit research programme is Makerere University. The position will be located at the School of Public Health alongside the research team for this workstream.

You would be working on a workstream aimed at improving perinatal bereavement care. Specifically, you will support testing of the hypothesis that; implementation of a multicomponent intervention including a staff bereavement education workshop, a bereavement 'champion' network and/or access to postnatal telephone peer support will reduce grief intensity for women after stillbirth or neonatal death to compared with existing care and support. 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 will be expected to travel within the districts where the study sites are located.

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 to 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

Knowledge, skills and experience

- Hold a Master's degree in a health-related field
- Hold a Bachelor's degree in a health-related field
- Experience of recent working in maternity care
- Research experience in an academic and/or relevant health care setting
- Good overall understanding of research methods and evaluation research
- Familiarity with data collection software, such as RedCap
- At least two years of relevant experience in clinical/community trials or a health-related research project
- Experience in social sciences or health research proposal writing, implementation and dissemination

Submission of applications

Applicants should use the application link provided to apply letter addressed to the Dean School of Public Health Makerere University, an updated curriculum vitae with an active phone number, two recommendation letters and 4 academic documents.

Application link: https://forms.gle/BLfHpMjKCgfPvW1e9

Closing date: 5th May 2023. Only short-listed candidates will be contacted for interviews.

Interviews: First week of June 2023

Resumption of duty: July 2023