EMPLOYMENT/CAREER OPPORTUNITY

The Unit is an internationally recognised centre of excellence with dominant research themes in the areas of HIV and emerging infections, vaccines and immunity, and chronic diseases and cancer. Through a multidisciplinary approach, intersecting basic science, epidemiological research, social-behavioural research and the conduct of new intervention evaluation studies, the Unit contributes knowledge on changing epidemics and diseases, the evaluation of innovative health care options, treatment and prevention and the development of health policy and practice in Africa and worldwide. Following the signing of strategic transfer agreements between the London School of Hygiene & Tropical Medicine (LSHTM) and the Medical Research Council (MRC UK), the Unit formally joined LSHTM on 1st February 2018. The exciting new partnership will boost research capacity into current and emerging health issues in Africa and throughout the world. The Unit is based at the UVRI Entebbe campus with established outposts in Kalungu, Masaka, Wakiso and Kampala Districts. The Unit is now seeking an enthusiastic and experienced individual to fill the following position:

Head of Research Governance (01 Position)

Position Code: HRG -820
Reports to: Unit Director (Uganda) & Head of Research Governance & Integrity (London)
Station: Entebbe
Duration: 2 years, renewable subject to availability of funds.

Job Purpose:

The overall purpose of this role is to establish, maintain and oversee a research governance framework and systems at the Unit that ensure compliance of the Unit’s research portfolio with;

a) Regulatory requirements;
b) Ethical requirements;
c) International standards of best practice; and,
d) LSHTM/Unit Standard Operating Procedures (SOP) and Policies.

- This includes all Unit research including laboratory research, data based research, human studies, pre-clinical and clinical research, including clinical trials, device studies and other interventional research at the field stations, partnering institutions, in the field throughout Uganda and occasionally in the region.
- The post holder is expected to establish internal ways of working and oversight mechanisms that achieve compliance with the above, and supports Principal Investigators, Project Leaders, Research Teams and Sponsors in achieving this.
- The post holder also effectively oversees research risks and provides summary reports that feed back into the corporate risk management structure.
- The role is responsible for providing excellent services, support and advice to research teams.
• The post holder acts as Sponsor representative for LSHTM-sponsored trials and studies at the Unit.

Roles & Responsibilities

1. **General duties:**

• Lead a team of research support specialists including Clinical Trial Monitors, Clinical Trial Assistants and Research Compliance Auditors.
• Ensure all research projects follow good research practice (GRP).
• Ensure appropriate and approved participant information and informed consent documents are being used for all research involving human participants, their data and samples.
• Establish departmental KPI and report progress to Unit Director quarterly.
• Maintain information systems that track research projects in the different categories (data only, samples and data, volunteers, patients, interventional research and clinical trials) and their relevant stages (e.g. start-up, active/recruiting, active follow-up, data cleaning, close-out, reporting).
• Retain oversight over Unit responsibilities and obligations towards external sponsors.
• Engage and collaborate with other Unit support service department to ensure they deliver work in compliance with applicable research requirements (e.g. Data Management, IT, Archives, Clinical Diagnostic Laboratory Services, Biobank and other departments).
• Ensure access to Unit data and biological samples (including the GPC) is controlled and governed by appropriate procedures (on-site and off-site).
• Work closely with the Unit’s Research Support Office to ensure department staff and additional costs (such as ethics review and regulatory fees) are appropriately budgeted for.
• Review and develop proposals for the improvement of internal research review and approval processes that cover scientific excellence, strategic fit, appropriate resourcing, compliance and outputs.
• Establish, maintain and monitor systems that ensure all research staff have the appropriate and documented level of skill and training to conduct their respective activities (in collaboration with Training Department and HR).
• Facilitate all types of research audits, including internal LSHTM audits and internal/external sponsor audits.
• Follow-up and resolve audit findings in a timely manner.
• Support regulatory inspections – remotely and on-site.
• Maintain systems that proactively identify non-compliances.
• Promptly and formally report and address non-compliances (including serious breaches and policy violations) by overseeing root cause analysis and Corrective Action Preventative Action (CAPA) plans.
• Follow-up non-compliances until resolution.
• Provide ad-hoc and summary reports of non-compliances to Unit management, LSHTM London and MRC/UKRI as applicable.
• Provide guidance and keep up to date Unit management and research teams on changes in national requirements or international standards ensuring that the Unit’s research portfolio continues to meet appropriate standards.
• Facilitate study team applications for research approval to Uganda National Council of Science & Technology (UNCST).
• Support teams in obtaining local and LSHTM ethics approvals.
• Ensure research/trial teams adhere to all reporting requirements and associated timelines.
• Provide ICH-GCP and other relevant trainings on best research practice at the Unit and occasionally to external stakeholder, as applicable.
• Maintain records and oversight of all study/trial amendments, ensuring that records are up to date.
• Undertake any other duties within the grade as required by the Unit.
• Represent Unit in meetings with external stakeholders on the national, regional and global level.

**Clinical Trial Oversight and Support:**

• Establish formal green light process for drug and vaccine trials at the Unit that ensures all necessary requirements are met prior to trial start.
• Provide technical advice and input on protocols on appropriate clinical trial procedures and regulatory/ethics requirements.
• In collaboration with trial teams ensure external research locations are fit-for-purpose (in collaboration with Estates and CDLS departments).
• Ensure trial teams are developing and implementing study-specific procedures (SSP).
• Facilitate trial team applications for trial approval to the National Drug Authority (NDA).
• Develop procedures that allow risk-based monitoring – both on-site and remotely.
• Oversee the development and implementation of formal, risk-based monitoring plans.
• Deliver internal clinical trial monitoring services independent from the research team and support external monitoring visits as needed.
• Ensure monitoring reports are generated and issued/received on time (inc. CAPA, as above).
• Provide centralized clinical trial support in multinational clinical trials and consortia.

**Research Risk Management:**

• Maintain formal Unit research risk registers to capture top-level research risks.
• Ensure research projects develop and keep up to date study/trial-specific risk registers.
• Ensure systems are in place and applied that minimize research risk across the portfolio.
• Ensure appropriate research agreements are in place (funding agreement, MDTA, collaboration/consortium agreements etc.) prior to start of any research activities.
• Implement green light process for clinical trials at the Unit (internal sign-off for study start after confirming Trial Master File has all essential documents, the approvals, in place).
• Report quarterly to Unit Management Committee on non-compliances, research portfolio and research risk.

**Research Involving Animals:**

• Develop and implement structures that ensure appropriate regulation, control and reporting of research projects involving animals.
• Ensure highest procedural and ethical standards are being adhered to at the Unit.
• Ensure the Unit complies with the 3Rs – Reduction, Refinement, Replacement.
• Ensure animal housing and husbandry standards comply with applicable international standards.
• Facilitate integration with and reporting to LSHTM Animal Welfare and Ethics Review Body (AWERB) in London.
**Unit Laboratories:**

- Oversee compliance with ISO15189, GCLP and other quality standards in the Unit laboratories, as applicable (in collaboration with CDLS department and other Unit laboratories).
- Support re-accreditation and maintenance of relevant standards (including re-accreditation visits and audits).

**Strategic planning:**

- Develop a formal strategy that ensures the department will meet the Unit’s evolving needs and overarching strategy.
- Anticipate department workload and regularly plan and adjust staff levels accordingly.
- Develop plans for a Clinical Trial Support sub-department which is to be primarily funded through external grants (this includes plans for employing in house Clinical Trial Monitors).
- Prepare business cases for initiatives that drive the development and improvement of the department and its services.
- Establish and maintain strong relationships and networks with partners in Uganda, the region and globally to share best practice and to develop new initiatives.

2. **Service Delivery:**

It is important that the Unit’s Research Governance services are delivered in a customer-oriented fashion. This post-holder ensures the department is;

- Responsive.
- Promptly communicating to users new developments such as new services, changes to services, service disruptions etc.
- Pro-actively resolving issues.
- Upholding high standards of professionalism.
- Ensure services are effective across all field stations, which requires regular direct interactions with staff outside Entebbe.
- Take responsibility for the overall quality of the service delivery.
- Lead the team’s self-assessment process supporting the team in setting targets and agreeing performance indicators for improvement.

3. **Financial Management and Cost Recovery**

The post holder is responsible for managing the department’s budget ensuring that:

- The available budget is effectively utilized to achieve the department’s and Unit’s wider objectives.
- Expenditure is carefully monitored and does not exceeded the allocated amount.
- Opportunities for cost recovery from research projects is maximized.
- The post holder approves expenditure in line with the Unit's delegated authority scheme (currently up to £5,000).
- There is full financial accountability.
- That all opportunities to achieve maximum value for money are realized.
4. **Line Management Responsibilities**

The post is line managing a group of diverse and specialized staff. The total staff number in the department is anticipated to reach fully operational levels over the next year and the department is expected to expand with a growing Unit research portfolio. Roles in the department include:

- Clinical Trial Monitors;
- Clinical Trial Assistants; and,
- Research Compliance Auditors.

The post holder ensures that

- Staff are enabled to perform their assigned duties as expected.
- Staff professional development is nurtured in line with the Unit’s and LSHTM’s capacity building goals.
- There is a positive and supportive work environment in the department.
- Staff feel included and valued and their professional feedback and proposals are heard and considered.
- Staff expectations are clearly communicated.
- Staff performance is regularly monitored.
- Potential conflicts are resolved promptly and decisively, involving HR support where needed.
- Formal appraisals are conducted within the departments in line with the Unit’s schedule.
- Applicable LSHTM and Unit HR policies are followed at all levels.
- Participate in the development of equal opportunities, diversity and inclusion.

5. **LSHTM Integration**

- Work towards integrating research governance and support services across LSHTM sites.
- Arrange monthly meetings with Head of Research Governance & Integrity (London).
- Provide routine and ad-hoc reports to Head of Research Governance & Integrity (London).
- Streamline approval and oversight process through LSHTM Ethics Online (LEO) by developing Unit specific templates and decision tree that facilitates integration and central oversight of Unit projects.
- Maintain excellent and supportive working relationship with Head of Research Governance at MRC Unit the Gambia at LSHTM.
- Proactively participate in meetings, committees and working groups across LSHTM sites and develop proposals to harmonise workflow.
- Ensure that the LSHTM ethics committee and other oversight bodies have overview of the Unit’s research activities.

6. **Environment**

- Develop strategies to reduce adverse environmental impact of the Research Governance department.
- Participate in carbon emission reduction activities across the Unit and wider LSHTM.
- Act as an advocate for the responsible and efficient use of resources.
Specifications:

- Postgraduate degree or professional qualification in a relevant field.
- Possession of a MSc in Clinical Trials or Clinical Trial Monitoring or PhD in a relevant field is desired.
- At least 5 years’ experience in a senior role in medical research related field.
- Minimum of 5 years’ experience in the design, conduct, analysis and reporting of clinical trials.
- Experience of collaborating with and managing multi-disciplinary project teams.
- Experience of advising and influencing others at senior level.
- Experience of budgetary control and reporting.
- Experience with pre-clinical research, inc. research involving animals is an added advantage.
- Should have expert knowledge of clinical trial methodology and regulatory requirements.
- Should possess formal training in ICH-GCP.
- Should have the ability to think strategically, for example in the planning of resources needed to oversee the portfolio of clinical trials to be undertaken at the Unit.
- Ability to work co-operatively with key stakeholders including Uganda Government agencies.
- Excellent writing skills and experience drafting protocols, reports, funding applications and regulatory documents.
- Proven track record of successfully negotiating clinical trial regulations.

How to Apply

Follow the link below to fill a form and submit your application documentation:

https://redcap.link/HeadOfResGovern

Filling the form more than once will lead to automatic disqualification. High level of integrity while filling the form is required and will be considered during shortlisting.

Deadline for application is **2nd September 2020, 5:00pm**. Only shortlisted candidates will be contacted for interview. This position is open to Ugandan nationals only. Strictly follow the application procedure as failure to do so will lead to automatic disqualification.

The applications should be addressed to:

The Head of Human Resources,
MRC/ UVRI and LSHTM Uganda Research Unit,
P.O. Box, 49,
Entebbe, Uganda.

Consider your application unsuccessful if not contacted within eight (8) weeks after the closing date of the advert. Any form of lobbying at any stage will lead to automatic disqualification. By submitting your personal information, you consent to the MRC/ UVRI and LSHTM Uganda Research Unit holding and using it in accordance with its recruitment policy and procedure. The Unit reserves the right to verify documents attached with the relevant awarding institutions to authenticate their validity.

**MRC/UVRI and LSHTM Uganda research Unit is an equal opportunity employer committed to having a diverse work force and does not ask for money at any stage of recruitment.**