NIHR Global Health Research Unit on Global Surgery

Hub Manager: Job Description & Responsibilities:

The Hub Manager will have operational control of the Hub and will be responsible for the smooth running of the portfolio of trials which will be delivered by the Global Surgery programme. This will include establishing trials within the Hub, gaining local approvals and establishing contracts with stakeholders as required (i.e. contracts with Spokes); key stakeholder engagement to ensure that relevant staff are aware of Hub activities and their role within those activities, within the Hub site and at Spoke hospitals; ensuring pathways and procedures are in place to enable each trial to run according to the protocol; financial oversight of funding received from the Sponsor and sent to Spokes, including budget management; reporting to the Sponsor and to local regulatory bodies as required.

Main Duties

- The overall coordination and management of the implementation of programme activities including establishing and maintain linkages with relevant partners and other stakeholders
- Development of implementation plans for the delivery of key project activities and outputs
- Mobilising partner organisations, stakeholders and Spokes as per the agreement and fulfilling project objectives
- Managing and mobilising human, material and financial resources of the programme and assessing the resource needs for project activities.
- Managing and maintaining appropriate information log on all aspects of the Hub operation
- Coordinating and liaising with relevant collaborators, project partners, project beneficiaries and other stakeholders for effective delivery of project activities and policy influence at local and national levels
- Communicating project performance to management and partners (including the Sponsor) via the principal investigator and directly

- Ensuring timely reporting and documentation to improve relationships and accountability to donors and other partners through quality reporting in consultation with the principal Investigator
- Preparing and submitting timely periodic programme narrative and financial reports
- Financial monitoring: Overseeing and submitting (as required) the audit trail as required by the Funder/contractor/sponsor, keeping records of assets and any Unit purchased goods/services for potential auditory checks
- Organising annual review and planning meetings with stakeholders to inform programme outcomes
- Organising Hub Trial Management Group meetings on quarterly basis
- Obtaining local approval(s) for any projects within the programme, and submitting amendments as necessary
- Ensuring a system is in place to arrange follow-up appointments for patients participating in FALCON and other Unit studies
- Ensuring that the trial is conducted in accordance with the protocol, associated standard operating procedures and Good Clinical Practice (GCP) guidelines
- Familiarity with and adherence to safety reporting requirements according to the trial protocol(s) and supporting documentation, including familiarity with serious breach, urgent safety measure and expedited reporting requirements.
- Ensuring a system is in place for the timely submission of trial data via the trial database, and ensuring that Spoke data is queried appropriately and in a timely manner.
- Oversight/reordering of intervention supplies at the hub and spokes as required, including maintaining accountability records for reporting to the Sponsor
- Maintain the Investigator Site File (ISF) and patient Case Report Form (CRF) files, ensuring that documentation is current and accurate
- Overseeing spoke activation activities; overseeing or conducting Due Diligence on Spoke sites, establishment of contracts between the hub and spoke hospitals for the different studies; organizing initial supply of interventions;

conducting a spoke site initiation visit; ensuring the spoke has all current trial documentation

- Hub and spoke management and monitoring (including development of monitoring plan)
- Close liaison with local Finance Officer to manage hub budget from the Sponsor and to ensure payments to spokes and patients are made in a timely manner
- Overseeing additional Unit staff (e.g. but not limited to Finance Officer, Data Manager, Research nurse)
- Assist in site audits and monitoring visits carried out by regulatory authorities or the Sponsor
- Coordinate and respond to queries received from the International Coordinating Centre (ICC) at Birmingham Clinical Trials Unit (BCTU)
- Assist with maintenance of accountability records, including retaining oversight of intervention supply stock levels at site
- Travel to Spoke sites to assist with site initiation and on-site monitoring visits as necessary
- Develop and maintain effective working relationships with all involved staff (investigators, nurses, data managers, hub management team, etc)
- Work autonomously to maximise recruitment into the trials
- Consider the training and educational implications of the protocol and work with the hub management group to develop appropriate strategies to meet these in order to ensure the safe and accurate implementation of the study by self and others (i.e. development of new standard operating procedures and standards)
- Maintain an up to date knowledge of information procedures to work to the requirements of Good Clinical Practice
- Demonstrate a continuous process of professional and personal development in order to develop own and others' skills and to be aware of changes in professional practice
- Participate in training of trial team members (i.e. investigators medical students, research nurses, data manager, finance manager, etc)
- Any other business in accordance to the requirements of the Unit.

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Knowledge, Skills, Qualifications & Experience Required

Essential

- Educated to degree level in a relevant area or equivalent experience
- Minimum of 3 years experience in project management, monitoring and evaluation and report writing
- Knowledge and understanding of research governance regulations, principles and guidelines including Good Clinical Practice, patient confidentiality, etc
- Excellent communication and listening skills with the ability to communicate effectively on many levels (including via phone and email)
- Good skills in building and strengthening partnership
- Fluent in English (verbal and written)
- Must have experience of working with multi- and interdisciplinary teams.
- Experience of people management
- Able to develop and acquire new skills as required
- Ability to delegate and work through others
- Very well organised, with good attention to detail
- Excellent time management skills with an ability to plan and prioritise
- Able to work independently, to prioritise their own workload to meet schedules and seek advice when necessary
- Able to work across professional team and organizational boundaries
- A flexible, team-working attitude
- Ability to work flexibly to meet service needs
- Computer literate and proficient in MS Office applications
- Willing to travel

Desirable

- Relevant post graduate experience in a research area or project

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- Fluent in other local languages or dialects, if applicable
- Experience in clinical trials
- Experience working with donor funded project
- Experience working with private sector
- Access to a vehicle which is suitable for work purposes

For informal query:

1. Dr Sonia Mathai : Sonia.mathai@tmckolkata.com
2. Dr Neha Desai : neha.desai@tmckolkata.com

You may apply on line or email your application by 29th November 2021 to above emails and to :

Mr Suvasish Mukherjee,
Head Human Resource, Tata Medical Center,
14 MAR (EW), New Town,
Rajarhat, Kolkata – 700160
suvashish.mukherjee@tmckolkata.com