MASSACHUSETTS GENERAL HOSPITAL
JOB DESCRIPTION

Job Title: Program Manager
Job Code: **Grade:**
Department/Unit/Section:
Reports To: Krista Dong

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FLSA Status:
Prepared by: Mary Dong
Reviewed by:
Date Last Revised:

GENERAL

The Ragon Institute of MGH, Harvard and MIT is seeking a full-time Program Manager to support the Females Rising through Education, Support and Health (FRESH) project, located in Durban, South Africa. The FRESH project is a unique research platform that combines basic science research with a social program to benefit study participants from an historically disadvantaged population. Research conducted at the FRESH clinical research site focuses primarily on HIV prevention and cure strategies and disease risk-factors associated with the vaginal microbiome.

This is a great opportunity for a highly motivated individual who is interested in working internationally, at the epicenter of the AIDS epidemic, on exciting new initiatives in HIV prevention and cure research. Requesting a minimum three-year commitment.

The Program Manager will manage daily operations at the FRESH clinical research site, leading a 30-person multi-disciplinary team in the execution of multiple existing (and future) projects in collaboration with the University of KwaZulu-Natal, Gates Foundation, IAVI, Gilead Sciences, and other partners. In this role, the Program Manager will: a) ensure research activities are conducted in accordance with study protocols and within prescribed timelines, b) manage regulatory submissions and compliance, c) plan and drive new project collaborations, and d) ensure that the research site is adequately staffed and equipped to execute all funded projects.

PRINCIPAL DUTIES AND RESPONSIBILITIES*:* Indicate key areas of responsibility, major job duties, special projects and key objectives for this position. These items should be evaluated throughout the year and included in the written annual evaluation.

Under the direction of the FRESH Clinical Director, the Program Manager will independently supervise and coordinate multiple departments, carry out daily activities, and drive large projects at the research site. This individual will be an active member of the Ragon in South Africa Operations Team contributing to the execution of Ragon intiatives in South Africa.

Responsibilities will include:

Project/Study Coordination

a. Develop and maintain research Standard Operating Procedures, CRFs and other research tools
b. Manage communication and logistics between the site, PIs, Sponsors, CROs, and processing labs
c. Provide support to the clinical team to conduct study visits, complete CRFs, and collect specimens, per protocols.

d. Ensure enrollment targets and project milestones are met
e. Ensure site is prepared for audits by Sponsors and CROs

Staff Supervision

a. Lead weekly staff meetings.
b. Assist Clinical Director with training, direction, guidance and support of staff in their roles and responsibilities
c. Conduct on-going assessment of their tasks, provide feedback.
d. Oversee annual staff performance review process
e. Assist with recruitment, interviews and hiring of new staff members as needed. Supervise orientation and ensure training requirements for new staff.
f. Assist the Clinical Director in the creation and maintenance of Delegation Logs, job descriptions and project organogram
g. Directly supervise and support the Site Coordinator in the following tasks
    - Ensure physical structure and all equipment are maintained and functioning properly
    - Oversee repair and maintenance, manage vendors.
    - Develop and manage inventory systems, insurance coverage/claims
    - Maintain communication and negotiate needs/issues with facility management
    - Develop and maintain Standard Operating Procedures (SOPs) for site management processes.
    - Coordinate events and meetings

Regulatory

a. For all studies, ensure research activities are conducted per approved protocols
b. Overall management of IRB submissions, including preparation and submission of protocol applications. This may also include assisting with protocol development, consent writing and preparation of recruitment and other study materials as required.
c. Assist with Quality Assurance and Quality Control internal audits to monitor regulatory compliance of investigators and research staff
d. Obtain Community Advisory Board (CAB) approvals to meet IRB requirements

Data Management

a. Manage data requests from PIs.
b. Supervise the Data Team and monitor Quality Control procedures to ensure accuracy and completeness of data collected
c. Ensure data is transmitted to Sponsors, within prescribed timelines

Community Engagement

a. Maintain communication with Community Advisory Boards (CABs) and organize regular research updates from PIs to ensure CAB is well-informed and supportive of all research activities
b. Work with the clinical team to develop and nurture strong relationships with local clinics/hospital where participants are referred for care

Communication

a. Initiate, coordinate, and lead meetings with Principal Investigators, Project/Study Coordinators and collaborating research scientists.
b. Respond to all requests for information and or documentation from Sponsors, PIs and CROs.

c. Facilitate communication between stakeholders on multiple projects.
d. Maintain close communication with the Clinical Director; provide frequent progress reports.

LICENSES, CERTIFICATIONS, and/or REGISTRATIONS (if applicable): Specify minimum credentials and clearly indicate if preferred or required

Good Clinical Practices (GCP) training certificate.
Program Management Professional (PMP) Certification a plus

EDUCATION: Specify minimum education and clearly indicate if preferred or required

BA or BSc required; MPH preferred

EXPERIENCE: Specify minimum creditable years of experience and clearly indicate if preferred or required

- 4+ years of experience as Program Manager/Senior Project Manager in clinical research environment. Clinical trial experience preferred.
- International work experience, a plus.
- Experience with Institutional Review Board (IRB) communications, including drafting and coordination of IRB submissions.

SKILLS/ ABILITIES/ COMPETENCIES REQUIRED: (MUST be realistic, measurable, objective, and related to the essential functions of the job.)

- Candidates must have demonstrated, outstanding project management skills in a clinical research environment.
- Able to manage IRB submissions and regulatory compliance with Investigators and other research staff
- Must be highly organized; self-motivated and assertive, with good problem-solving ability
- Ability to work independently and as a team member, in fast-paced, demanding, clinical research environment in an effective and flexible manner.
- Must have excellent written and verbal communication skills.
- Expertise with Microsoft Office programs is essential
- Willing to be based full-time in Durban, South Africa. Minimum 3-year commitment
- Flexibility to occasionally work evenings or weekends
- Strong candidates have a demonstrated interest in HIV and/or women's health initiatives

WORKING CONDITIONS: Describe the conditions in which the work is performed.

This is a full-time position in Durban, South Africa. Work is to be performed on-site, daily, at the FRESH Clinical Research Site, located in the Umlazi township.

APPROVAL:

Name: Title: Date

The above is intended to describe the general contents and requirements of work being performed by people assigned to this classification. It is not intended to be construed as an exhaustive statement of all duties, responsibilities or skills of personnel so classified.