POSITION DESCRIPTION

POSITION TITLE:	Clinical Trials Project Manager / Senior Clinical Trials Project Manager
CLASSIFICATION:	SO4/SO5
DIVISION:	Biology
DEPARTMENT:	Clinical Tropical Medicine (CTM)
PROGRAM:	Infectious Diseases
LOCATION:	Herston

Position Objectives

The primary objectives of this position are to:

1. Develop documentation for clinical trials and study reports that are compliant with ICH GCP requirements.
2. Ensure the clinical trials are conducted effectively and efficiently as per agreed timelines, including assisting in the management of resources and activities.

Organisational Context

QIMR Berghofer is a statutory body under the QIMR Act (1945). The mission of QIMR Berghofer is to promote the wellbeing of humankind through medical research, to maintain within the State of Queensland an internationally recognised Centre for Medical Research, to develop that Centre as the primary focus of Medical Research within the State and to co-operate with, and where possible assist the work of other medical research establishments within the State and throughout the world.

Clinical Tropical Medicine investigates how parasites such as the malaria parasite, hookworm, threadworm and scabies cause disease and how they become resistant to drugs used to treat them. The group also identifies new drugs and drug targets, and develops novel diagnostic techniques. A program of human clinical trials testing malaria drugs and vaccines involves infecting human volunteers with malaria. As such, a comprehensive suite of documentation needs to be prepared for each study and careful project management is required.

Reporting Structure

This position reports to the Head of Clinical Research. In addition, the role will be required to work closely with other senior members of the CTM leadership team and related groups.

Primary Responsibilities

- Manage clinical trial projects ensuring that they are conducted efficiently, to the required standard and within proposed time frames.
- Define tasks effectively, and identify, schedule, and prioritize activities, as well as monitor and report on projects' progress.
- Create, implement and maintain documentation and procedures for clinical trials, ensuring compliance with relevant regulations (ICH GCP, TGA, HREC, Safety, QIMR Berghofer's policies and procedures for Clinical Research and other organisational procedures). These include: assisting in the design of clinical trial protocols, clinical trial forms/templates and associated documents and procedures for HREC submissions and amendments.
- Write protocols, clinical study reports and grant applications for supervisors, collaborators and external organisations.
- Liaise with members of the CTM team, clinicians, clinical trial coordinators, internal and external collaborators, to ensure studies progress on schedule and adequate resources are allocated to complete the trial within specified deadlines and budget.
- Monitor clinical trial activities to ensure compliance with the Institute's ethical and biosafety requirements and other legislative requirements.
- Ensure work practices comply with the requirements of the *Work Health and Safety Act*, related legislative requirements and the Institute's WH&S policies and procedures.

Key Selection Criteria (Qualifications, Experience, Skills, Abilities and Personal Qualities)

Essential

- Highly motivated individual with a minimum of a Bachelor's degree in Biomedical Science or other relevant discipline.
- Experience in clinical trial project management, particularly in planning and implementation of complex projects involving partners in multiple disciplines including regulatory authorities.
- High level written communication skills with experience in preparing clinical study reports and clinical trial protocols, and analysing information from multiple sources.
- Excellent organisational and time management skills.
- High level attention to detail, particularly in handling data and record keeping.
- Excellent verbal and interpersonal communication skills.
- Detailed knowledge of ICH Guidelines and GCP.

Desirable

- Experience in managing early phase clinical trials.
- At least 5 years' experience in clinical trial project management

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