Position Description

Clinical Project Coordinator

Position Number: 00083741 *Position Title: Clinical Project Coordinator* *Date Written: March 2020*	*Faculty / Division: UNSW Medicine* *School / Unit: Kirby Institute, TVRP* *Position Level: Level 7*

ORGANISATIONAL ENVIRONMENT

UNSW is currently implementing a ten-year strategy to 2025 and our ambition for the next decade is nothing less than to establish UNSW as Australia's global university. We aspire to this in the belief that a great university, which is a global leader in discovery, innovation, impact, education and thought leadership, can make an enormous difference to the lives of people in Australia and around the world.

Following extensive consultation in 2015, we identified three strategic priority areas. Firstly, a drive for academic excellence in research and education. Universities are often classified as 'research intensive' or 'teaching intensive'. UNSW is proud to be an exemplar of both. We are amongst a limited group of universities worldwide capable of delivering research excellence alongside the highest quality education on a large scale. Secondly, a passion for social engagement, which improves lives through advancing equality, diversity, open debate and economic progress. Thirdly, a commitment to achieving global impact through sharing our capability in research and education in the highest quality partnerships with institutions in both developed and emerging societies. We regard the interplay of academic excellence, social engagement and global impact as the hallmarks of a great forward-looking 21st century university.

To achieve this ambition, we are attracting the very best academic and professional staff to play leadership roles in our organisation.

VALUES IN ACTION: OUR UNSW BEHAVIOURS

UNSW recognises the role of employees in driving a high-performance culture. The behavioural expectations for UNSW are below.

Values in Action
Our UNSW Behaviours

Demonstrates Excellence	Delivers high performance and demonstrates service excellence.
Drives Innovation	Thinks creatively and develops new ways of working. Initiates and embraces change.
Builds Collaboration	Works effectively within and across teams. Builds relationships with internal and external stakeholders to deliver on outcomes.
Embraces Diversity	Values individual differences and contributions of all people and promotes inclusion.
Displays Respect	Treats others with dignity and empathy. Communicates with integrity and openness.

OVERVIEW OF RELEVANT AREA AND POSITION SUMMARY

UNSW Medicine is a national leader in learning, teaching and research, with close affiliations to a number of Australia's finest hospitals, research institutes and health care organisations. With a strong presence at UNSW Kensington campus, the faculty have staff and students in teaching hospitals in Sydney as well as regional and rural areas of NSW including Albury/Wodonga, Wagga Wagga, Coffs Harbour and Port Macquarie.

The Kirby Institute is a leading global research institute dedicated to the prevention and treatment of infectious diseases. Established in 1986 in response to the then emerging HIV epidemic, the Kirby Institute now contributes to knowledge on a broad range of diseases, including viral hepatitis and sexually transmissible infections. Focussing on the coordination of national surveillance programs, population health and epidemiological research, clinical and behavioural research and clinical trials, the Kirby Institute's research projects are conducted in partnership with communities most affected by epidemics.

The Kirby Institute aims to find ways to control infections, develop new therapies and preventative vaccines, as well as providing critical leadership to decision makers in Australia and internationally on the most effective, efficient and sustainable strategies to address epidemics.

The Therapeutic and Vaccine Research program conducts clinical studies across a range of infectious and immunologic diseases, including HIV, infection-related cancers, influenza and COVID-19. Our team provides global leadership through our role as an International Coordinating Centre for the INSIGHT network and collaborations with UNITAID at the World Health Organization, the U.K. Medical Research Council, and the National Cancer Institute and National Institute of Allergy and Infectious Diseases at the U.S. National Institutes of Health.

The Clinical Project Coordinator is responsible for set up, coordination and monitoring of clinical research projects, conducted by the Kirby Institute. This may include both international and domestic studies (including those in low and middle-income countries).

The role of Clinical Project Coordinator reports to Head of Therapeutic and Vaccine Research Program (TVRP) and has no direct reports.

RESPONSIBILITIES

Specific responsibilities for this role include:

- Ensure that studies conducted by the Therapeutic and Vaccine Research Program maintain high scientific and ethical standards in accordance with International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) requirements. Prepare key study materials including case report forms, ethics applications, essential documents, study procedure manuals and study newsletters
- Ensure that clinical trials and registry studies conducted by the Kirby Institute are well supported by assisting clinicians, nurses, laboratory staff and other allied health personnel in data collection, specimen collection and retention of study patients thru effective communication. Develop strategies to ensure effective and efficient management and analysis of research data, including remote data monitoring and liaison with data entry and data management staff to maintain current, complete and accurate trial databases.
- Travel to sites (either national or international) participating in the study to perform on-site monitoring and coordination duties. This will include 'virtual/remote' monitoring' during COVID-19 pandemic.
- Ensure that patient assessments are performed according to the study protocol by verifying that medical records are complete and that data collection instruments are accurate by comparing with original source documents, according to International Conference on Harmonisation -–Good Clinical Practice (ICH GCP) requirements as defined by the relevant standard operating procedures.

- Supervise the maintenance of study documents at the Kirby Institute and provide interpretation of study documents to sites and institutions such as ethics committees as required.
- Liaise with participating institutions, clinicians and pharmaceutical companies regarding the study requirements and adherence to SOP defining procedures relating to study drugs (where applicable).
- Conduct pharmacovigilance activities including liaison with sites for the collection of supporting documentation for Serious Adverse Events, liaison with the Medical Officer, Pharmaceutical companies and HREC.
- Provide guidance to individuals and teams preparing other study documentation and instrumentation.
- Provide guidance and support to others involved in coordination of individual research projects.
- Cooperate with all health and safety policies and procedures of the university and take all reasonable care to ensure that your actions or omissions do not impact on the health and safety of yourself or others.

SELECTION CRITERIA

- Graduate biomedical science qualifications or other medical qualifications including nursing or an equivalent level of knowledge gained through any other combination of education, training and/or experience.
- A strong knowledge of Good Clinical Research Practice Guidelines with substantial relevant experience in the conduct of clinical research.
- Demonstrated management of clinical trial data and clinical trial databases, and research specimen collection.
- Demonstrated experience undertaking ethical and regulatory submissions, coordinating and monitoring clinical trials in Australia. International experience, particularly in low-middle income countries would be well regarded.
- Demonstrated experience in contract development and management.
- Demonstrated experience contributing to the preparation of conference presentations and manuscripts.
- Experience with interim and final study reports including analysis plans.
- Demonstrated experience coordinating and running project team meetings.
- Excellent organisational, analytical and problem-solving skills, with the proven capacity to work independently and meet deadlines.
- Ability to travel locally, interstate or overseas when required.
- Excellent computer skills with Microsoft Office with a proven aptitude for learning new software packages, accessing research publications and searching relevant databases.
- Knowledge of health and safety responsibilities and commitment to attending relevant health and safety training.

It is not the intention of the position description to limit the scope or accountabilities of the position but to highlight the most important aspects of the position. The aspects mentioned above may be altered in accordance with the changing requirements of the role.