Make it matter.

POSITION DESCRIPTION

Clinical Project Coordinator

Position Level	7
Faculty/Division	Medicine
Position Number	00047899
Original document creation	4/1/ 2021

Position Summary

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 Viral Hepatitis Clinical Research Program (VHCRP) is one of the largest research programs within the Kirby Institute. The program focuses on therapeutic research in viral hepatitis, including research into HIV/Hepatitis co-infection. The program also has a substantial laboratory research sub-program which utilises samples collected within hepatitis clinical protocols. VHCRP liaises with the other programs within the institute, as well as with hepatologists, infectious disease physicians, primary care networks, and laboratory groups nationwide. The VHCRP is responsible for the management and co-ordination of a large number of studies across an extensive network of national and international clinical sites where the studies are performed.

The Clinical Project Coordinator is responsible to the Head of the Viral Hepatitis Clinical Research Program for the coordination, management and monitoring of clinical trials within the program which will involve participants from sites in Australia and overseas. The position holder will use their experiences in biomedical research to devise, implement, monitor and report on the conduct of research projects from inception and provide strategic and tactical guidance on operational matters.

The role of Clinical Project Coordinator reports to Head of the Viral Hepatitis Clinical Research Program and will work closely with the VHCRP Clinical Trials Manager. This position has no direct reports.

Accountabilities

Specific accountabilities for this role include:

- Prepare key study materials including the protocol, case report forms, ethics application, essential documents and study procedure manuals
- Provide interpretation of study documents to sites and institutions such as ethics committees as required
- Travel to sites participating in the study to perform on-site monitoring and coordination duties
- 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
- Prepare proposed study budgets and obtain both financial and investigator agreements for Kirby Institute trials
- Liaise with participating institutions, clinicians and funding bodies regarding the study requirements
- Manage the study budget and provide data reporting when required
- Supervise maintenance of trial records by clerical staff at the Kirby Institute and identify inaccuracies or problems in completion of data forms and OpenClinica appropriate staff
- Contribute to the development of analysis plans for the Institute's trials and present study data at both national and international forums with private and public sector groups or agencies
- Provide guidance to other colleagues within and without defined project teams on operational matters in clinical research
- Participate in other activities of the Viral Hepatitis Clinical Research Program as required
- Align with and actively demonstrate the UNSW Values in Action: Our Behaviours and the UNSW Code of Conduct.
- 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.

Skills and Experience

- Graduate biomedical science qualifications or other medical qualifications including Nursing and subsequent relevant experience in the conduct of multicentre clinical trials, or an equivalent level of knowledge gained through any other combination of education, training and/or experience
- Demonstrated management of clinical trial data and clinical trial databases, and research specimen collection
- Willingness and ability to travel locally and interstate on a regular basis
- Excellent computer skills with Microsoft Office with a proven aptitude for learning new software packages, accessing research publications and searching relevant databases
- Proven experience drafting and managing budgets, and experience with interim and final study reports including analysis plans

- Demonstrated experience coordinating and running project team meetings, protocol steering committee meetings and investigator start-up meetings
- Demonstrated experience completing ethical and regulatory applications for clinical trials, both nationally and internationally
- Demonstrated experience with site clinical trial research agreement development, vendor selection and contract management
- An understanding of and commitment to UNSW's aims, objectives and values in action, together with relevant policies and guidelines.
- Knowledge of health and safety responsibilities and commitment to attending relevant health and safety training

About this document

This Position Description outlines the objectives, desired outcomes, key responsibilities, accountabilities, required skills, experience and desired behaviours required to successfully perform the role.

This template is not intended to limit the scope or accountabilities of the position. Characteristics of the position may be altered in accordance with the changing requirements of the role.