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POSITION DESCRIPTION

Clinical Project Coordinator

Position Level	7
Faculty/Division	Medicine & Health
Position Number	00099209
Original document creation	8/11/2021

Position Summary

The Kirby Institute is a world-leading health research institute at UNSW Sydney. We work to eliminate infectious diseases, globally. Our specialisation is in developing health solutions for the most at-risk communities. Putting communities at the heart of our research, we develop tests, treatments, cures and prevention strategies that have the greatest chance of success.

The Clinical Project Coordinator is responsible for the coordination, management, and monitoring of trials. 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.
- Perform and monitor patient assessments according to the study protocol including verifying medical records are complete and that data collection instruments are accurate andensuring assessments are conducted in accordance to International Conference on Harmonisation

guideline for 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 Viral Hepatitis Clinical Research Program 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 in the Viral Hepatitis Clinical Research Program and identify inaccuracies or problems in completion of data forms and OpenClinica.
- 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.
- Provide Clinical Project support to 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.
- 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.

- Excellent time management skills, with a demonstrated ability to respond to changing priorities, manage multiple tasks and meet competing deadlines by using judgement and initiative.
- Excellent written and verbal communication skills, with a high level of attention to detail for deliverables produced.
- 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.

Additional Requirements

- Willingness and ability to travel locally and interstate on a regular basis.

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.