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POSITION DESCRIPTION

Senior Clinical Data Manager

Faculty/Division	Medicine & Health
Classification Level	Professional 8
Hours & Span (Category)	G - Administrative, Clerical, Computing, Professional & Research Staff
Position number	00155782
Shiftwork status	NOT SHIFTWORKER
Allowances	N/A
On call arrangements	N/A
Original document creation	31 May 2024

Position Summary

The CRU was launched in 2023 to support academic researchers to have the relevant expertise, systems, and tools to allow efficient, high quality, impactful research to be conducted across UNSW and its affiliated networks.

The Senior Clinical Data Manager is a member of the Clinical Research Unit (CRU) operations team and will have overall leadership and responsibility for developing and implementing high quality data management systems and processes to ensure data compliance, integrity, and security. The role will require stakeholder management with key groups within UNSW, affiliated Medical Research Institutes (MRIs) and across the UNSW network to ensure quality data management service delivery. Key stakeholders include Division of Research and Enterprise, UNSW IT, the Kirby Institute and The George Institute for Global Health.

The Senior Clinical Data Manager reports to the Program Operations Lead and has one direct report.

Accountabilities

Specific accountabilities for this role include:

- Lead and manage CRU data management projects including assessment, selection, implementation and support of systems and tools that support UNSW clinical research projects against researcher, regulatory and UNSW requirements and make recommendations for improvements and implementation. Systems and tools include electronic data management solutions, clinical trial management systems and new technologies supporting clinical research.

- Develop methods to assess impact of CRU Data Management services on stakeholders inform future service delivery models.
- Provide expert technical input into development of novel approaches to clinical research data including possible integration of Electronic Data Capture (EDC) with Electronic Medical Records, Decentralised clinical trials, and adaptive platform trials.
- Provide high level data management recommendations and expert support to multiple stakeholders including CRU Steering Committee and researchers accessing CRU services. Expert advice and support for researchers will include design, build and maintenance of appropriate data warehouse structures as well as appropriate documentation (data management and validation plans) to ensure data collection, cleaning and reporting are high quality and in compliance with study protocol, SOPs, ethics and regulatory requirements.
- Lead the development of a suite of CRU Data Management Standard Operating Procedure (SOPs) and tools that align with wider UNSW data handling policies and tools to ensure clinical research conducted by the CRU is high quality, compliant and secure.
- Identify gaps current in data management training opportunities and develop, conduct and review robust data management training programs with the CRU Training Manager, Division of Research and Enterprise and UNSW IT.
- Provide mentorship on the technical and process aspects of clinical data management to team members, researchers, and collaborators across UNSW Faculty of Medicine, and affiliate organisations.
- Promote awareness and knowledge of high quality, compliant and secure data management solutions to UNSW Faculty of Medicine researchers, through the CRU.
- Collaborate effectively with multiple stakeholders across UNSW and affiliate organisations to plan, develop and deliver on CRU data management requirements.
- Perform other duties as assigned by supervisor.
- Align with and actively demonstrate the [Code of Conduct and Values](#)
- Ensure hazards and risks psychosocial and physical are identified and controlled for tasks, projects, and activities that pose a health and safety risk within your area of responsibility.

Skills and Experience

- Tertiary qualifications in a health-related field or computer qualifications. Post-graduate qualifications highly desirable.
- Extensive relevant experience (> 7 years) in clinical research data management, including experience in the development of clinical study databases and data management documentation such as SOPs and data management plans, preferably in an academic setting.
- Extensive experience with a wide range of clinical research electronic data capture platforms. Experience with REDCap and Medrio and CTMS will be advantageous.
- Extensive demonstrated knowledge of International Council for Harmonisation Good Clinical Practice Guidelines (ICH-GCP) and their application to Good Clinical Data Management.
- Demonstrated high level critical thinking, analytical and problem-solving skills.
- Demonstrated ability to work effectively with a range of stakeholders and to negotiate and influence as a means of obtaining desired outcomes.

- Excellent communication skills with the ability to clearly convey ideas and information to a wide range of stakeholders through presentations, written communication, and other means.
- Excellent organisational and time management skills and demonstrated ability to manage and respond to changing priorities and deadlines.
- An understanding of and commitment to UNSW's aims, objectives and values in action, together with relevant policies and guidelines.
- Knowledge of health & safety (psychosocial and physical) responsibilities and commitment to attending relevant health and safety training.

Pre-employment checks required for this position

- Verification of qualifications

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.