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POSITION DESCRIPTION

Clinical Trials Research Governance Officer

Faculty/Division	DVC-Research and Enterprise
Classification Level	Professional 7
Hours & Span (Category)	G - Administrative, Clerical, Computing, Professional & Research Staff
Position number	ADMIN ONLY
Shiftwork status	NOT SHIFTWORKER
Allowances	N/A
On call arrangements	N/A
Original document creation	October 2020

Position Summary

The Clinical Trials Research Governance Officer plays an integral role within the Division of Research & Enterprise in providing advanced clinical trials governance support to the Human Research Manager and the Director, Research Ethics Compliance.

The role will oversee the compliance and regulatory requirements to facilitate assessment, initiation, and continued monitoring of clinical trials in accordance with the UNSW requirements. The Clinical Trials Research Governance Officer significantly contributes to strategic and operational projects across the Research Ethics Compliance Support office supporting the delivery of Division of Research & Enterprise goals.

The role reports to the Human Research Manager and has no direct reports.

Accountabilities

Specific accountabilities for this role include:

- Ensure compliance with regulatory frameworks for ethical review and monitoring of UNSW sponsored clinical trials and contribute to the preparation of reports to regulatory bodies (such as the Therapeutic Goods Administration, NHMRC and the UNSW Governance Board).

- Proactively promote awareness of clinical trial research governance requirements among student, researchers, and stakeholders through the provision of Good Clinical Practice accredited courses, and/or high-profile education initiatives in both face to face and online environments.
- Undertake compliance reviews of proposed clinical trials and provide extensive advice to the Human Research Ethics Coordinator on whether trial meets regulatory, insurance, legal and UNSW requirements
- Manage submission of clinical trial notifications, including the invoicing process for the Therapeutic Goods Administration online portal.
- Significantly contribute to the development and implementation of guidelines, policies, procedures that will enhance the clinical trial research governance review and monitoring processes.
- Use expert analytical skills to prepare and manage the processing of proposals for UNSW to sponsor clinical trials for assessment by the UNSW Sponsor's Delegate.
- Develop and monitor the delivery of projects and initiatives to achieve operational and strategic goals across the Research Ethics Compliance Support Office.
- Support with the resolution of complex problems and enquiries, including coordinating high-level responses to complaints, reports of non-compliance, safety reports relating to clinical trials.
- 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 psychosocial or physical health and safety of yourself or others.

Skills and Experience

- Relevant tertiary qualification with a depth of subsequent experience in a clinical trials research governance environment or equivalent competence gained through any combination of education, training, and experience.
- High-level knowledge of codes and legislation related to clinical trials and research governance, along with skills to interpret accordingly.
- Demonstrated experience with safety monitoring and compliance reporting processes for clinical trials.
- Ability to analyse clinical trial and research related policies or guidelines and provide guidance to all stakeholders through the clinical trials research governance process.
- Advanced written and verbal communication skills, with a high level of attention to detail, experience with generating formal and complex meeting minutes and communications.
- High level organisational skills with proven ability to deal with multiple tasks, establish priorities and meet deadlines and the ability to operate autonomously.
- Advanced level of computer literacy, working with a range of computer systems and applications, including Microsoft 365
- 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.

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.