

Position Description

Position title:	Research Governance and Compliance Lead
Department:	Research Office
Classification:	Administration Officer Grade 6 (AO61-AO65)
Agreement:	Health and Allied Services, Managers and Administrative Workers (Victorian Public Sector) (Single Interest Employers) Enterprise Agreement 2025-2027
Reporting to:	Research Manager

About us

Located in Melbourne on the traditional lands of the Wurundjeri people of the Kulin Nation, the Royal Women's Hospital is Australia's first and leading specialist hospital for women and newborns. We offer expertise in maternity services, neonatal care, gynaecology, assisted reproduction, women's health and cancer services. We advocate for women's health in areas that have long been overlooked or stigmatised, including abortion, endometriosis, family violence, female genital mutilation, menopause, women's mental health, sexual assault and substance use in pregnancy.

Our vision, values and declaration

The Women's vision, values and declaration reflect our promise to our patients and consumers, and articulate our culture and commitment to our community and each other.

Our vision is '**Creating healthier futures for women and babies**'. Our values are:



Courage



Passion



Discovery



Respect

The Women's declaration reflects the principles and philosophies fundamental to our hospital, our people and our culture.

- **We are committed to the social model of health**
- **We care for women from all walks of life**
- **We recognise that sex and gender affect health and healthcare**
- **We are a voice for women's health**
- **We seek to achieve health equity**

Our commitment to inclusion

The Women's is committed to creating and maintaining a diverse and inclusive environment which enhances staff and consumer wellbeing, and nurtures a sense of belonging. We strongly encourage anyone identifying as Aboriginal and/or Torres Strait Islander to join us. We offer a range of programs and services to support First Nations employees. We invite people with disability to work with us, and we welcome anyone who identifies as linguistically, culturally and/or gender diverse, people from the LGBTQIA+ community and people of any age.

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About the department/unit

The Research Governance and Compliance Lead will be part of the Women's Research Office.

The Women's is committed to improving the health and wellbeing of women and newborns through its internationally recognised research and innovation. We have a distinguished track record in medical research, and this is reflected by the breadth of our programs.

Covering the full spectrum of our work are our 10 research centres: newborn, infectious diseases, gynaecology, cancer, pregnancy, mental health, midwifery and maternity services, allied health, anaesthetics and family violence prevention.

Annually we conduct approximately 60 clinical trials involving more than 4,500 patients and produce approximately 200 publications.

As a tertiary-level hospital and one of Australia's major teaching hospitals for graduates and postgraduates in medicine, nursing, midwifery and other health professions, the Women's provides a clinical environment where scientists and health professionals can work together as innovative leaders in translational research. Our partnerships with international hospitals and research centres assist us to deliver world-class health care for women and newborns and ensures our model of care is at the forefront of modern clinical practice.

Position purpose

The Research Governance and Compliance Lead is responsible for the continuous improvement of key governance and compliance processes related to the conduct of clinical research at The Royal Women's Hospital. The role will oversee the implementation of the National Clinical Trials Governance Framework (NCTGF) and ensure the Women's is compliant with the framework. The role will:

- provide subject matter expertise and support to The Royal Women's Hospital research and professional staff regarding the NCTGF
- ensure compliance with the NCTGF and all other relevant codes and regulations
- develop policies and procedures, as well as appropriate reporting to ensure compliance
- coordinate activities and roles that will contribute to implementation of the NCTGF.

The role will be required to participate in the functions of the Research Office including policy development, Key Performance Indicator Reporting, auditing of practice, promoting a culture of safety and quality, and arranging training and education to The Royal Women's Hospital staff to support these functions.

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Key responsibilities

Leadership

- Provide responsive and effective advice and support to internal stakeholders across the Women's research community and the research office.

System Improvements

- Maintain a good working knowledge of clinical research related regulations, codes and guidelines in particular the NCTGF and take the initiative to coordinate activities related to compliance with the framework
- Assess and implement systems to ensure NCTGF standards are understood and met for accreditation
- Develop and review relevant internal policies, procedures, guidelines and SOPs to ensure compliance with the NCTGF
- Promote and maintain organisational readiness for external reviews of clinical research compliance and ACHS accreditation
- Coordinate annual gap analysis against the clinical research related regulations, codes, guidelines and the National Clinical Trial Governance Framework
- Prepare reports and presentations for delivery at key committees
- Undertake improvement activities as required

Education and Training

- Support the Research Manager to develop education and training programs in research quality, in collaboration with the
- Review, update and create tools to assist staff and managers prepare for external and internal reviews

Monitoring compliance including audit and KPI reporting

- Collect and analyse data based on audits designed to address compliance with clinical research related regulations, codes, guidelines and the NCTGF
- Develop contemporary internal audit schedules in line with research related regulations, codes and guidelines and the NCTGF.
- Provide detailed reports on audit findings to relevant committees and work with key stakeholders to implement improvement actions as required

Governance

- Support the Research Manager to establish and maintain appropriate governance to oversee the implementation and quality improvement of the NCTGF and to monitor gaps and ensure compliance and accreditation.
- Coordinate appropriate working groups and steering committees, preparing agendas, meeting reports and minutes as required

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Other Responsibilities

- Be aware of and work in accordance with Hospital policies and procedures, including Occupational Health and Safety, Equal Employment Opportunity and Confidentiality.
- Be respectful of the needs of patients, visitors and other staff and maintain a professional approach to all interactions.
- Development and review of relevant internal policies, procedures, guidelines and Standard Operating Procedures (SOPs).
- Undertake any additional tasks as requested that reasonably fall within the scope of the position and classification

Key Performance Indicators (KPI's)

KPI's are how you will be measured as meeting the responsibilities of the position. These will be set with you as part of your Performance Development Plan within the first six months of your appointment to the position.

Key selection criteria

Experience/qualifications/attributes

Essential:

- Tertiary Qualification in Health Care, Science or relevant discipline
- Experience with the conduct of clinical trials including commercially sponsored trials
- Experience in quality or risk in a clinical research environment
- Experience in implementation of the National Clinical Trials Governance Framework
- Demonstrated experience in systems and processes for achieving continuous quality improvement and audit
- Comprehensive understanding of research related regulations, codes, and guidelines and associated compliance requirements
- Demonstrated understanding of the principles and practices of research governance and ethics along with the related regulatory and policy environment including the National Clinical Trials Governance Framework and GCP.
- Highly developed communication skills with the ability to work collaboratively with external partners, and staff at all levels of the organisation
- Demonstrates strong interpersonal skills, including consultation, active listening, responsiveness and accessibility.
- Proven capacity to define and reconcile complex and competing priorities, together with the ability to identify and engage key stakeholders in addressing the same.
- Excellent writing skills including a demonstrated ability to prepare reports using clear, concise language; organise information into a logical sequence and include content fit for purpose
- Advanced computer literacy, including proficiency in Microsoft Office applications (Word, Excel and PowerPoint).

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Desirable:

- Post Graduate qualification in a science or health related field
- Experience in developing and implementing research governance, and/safety and quality initiatives
- Experience working within a hospital quality and safety framework, including accreditation readiness, research or clinical governance, quality improvement activities, audit processes and risk management.
- An understanding of medical conditions and their terminology
- An understanding of the requirements for informed consent
- An understanding of the patient populations including cultural and religious diversity.

Attributes

- Commitment to the Women's Declaration and strategic directions.
- A strong interest in and commitment to women's health, and understand the impact of social determinants on health and wellbeing.
- A strong results orientation.
- Applies sound judgement, maintains a professional approach, and effectively manages competing priorities to achieve results.
- Balancing sometimes competing and conflicting priorities.
- Committed to ongoing professional development, and continually identifies professional development goals & pursues opportunities for learning
- Values reflective practice / learning and accesses support, assistance, advice and debriefing as required.

Organisational relationships**Internal relationships**

- Research Office
- Quality and Safety
- Executive – Chief Medical Officer

External relationships

- Clinical Trial quality teams across the Parkville Precinct and across Victoria
- National Health & Medical Research Council
- Therapeutic Goods Australia
- Relevant Ethics and Governance offices in partner organisation
- Academic funding agencies
- Australian Commission of Safety and Quality in Health Care
- Other relevant regulators and external auditors

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Inherent requirements

Inherent requirements are the essential tasks and activities that must be carried out in order to perform this role, including with adjustments. The Women's is committed to providing workplace adjustments that support all people to work with us. We welcome you to discuss any adjustments with the manager of this role during the recruitment process or at any time during your employment, as we acknowledge and understand circumstances can change. You can also request a copy of our workplace adjustments procedure for more information.

Physical demands	Frequency
Shift work – rotation of shifts – day, afternoon and night	N/A
Sitting – remaining in a seated position to complete tasks	Prolonged/Constant
Standing – remaining standing without moving about to perform tasks	Rare
Walking – floor type even, vinyl, carpet,	Rare
Lean forward/forward flexion from waist to complete tasks	Rare
Trunk twisting – turning from the waist to complete tasks	Rare
Kneeling – remaining in a kneeling position to complete tasks	Rare
Squatting/crouching – adopting these postures to complete tasks	Rare
Leg/foot movement to operate equipment	Rare
Climbing stairs/ladders – ascending and descending stairs, ladders, steps	Rare
Lifting/carrying – light lifting and carrying less than 5 kilos	Frequent
– Moderate lifting and carrying 5 – 10 kilos	Rare
– Heavy lifting and carrying – 10 – 20 kilos.	N/A
Push/pull of equipment/furniture – light push/pull forces less than 10 kg	Frequent
– moderate push / pull forces 10 – 20 kg	Rare
– heavy push / pull forces over 20 kg	N/A
Reaching – arm fully extended forward or raised above shoulder	Rare
Head/neck postures – holding head in a position other than neutral (facing forward)	Rare
Sequential repetitive actions in short period of time	Rare
– Repetitive flexion and extension of hands wrists and arms	Frequent
– Gripping, holding, twisting, clasping with fingers/hands	Frequent
Driving – operating any motor-powered vehicle with a valid Victorian driver's license.	Rare
Sensory demands	Frequency
Sight – use of sight is integral to most tasks completed each shift	Prolonged/Constant
Hearing – use of hearing is an integral part of work performance	Prolonged/Constant
Touch – use of touch is integral to most tasks completed each shift	Prolonged/Constant
Psychosocial demands	Frequency
Observation skills – assessing/reviewing patients in/outpatients	N/A
Problem solving issues associated with clinical and non-clinical care	Prolonged/Constant
Working with distressed people and families	N/A
Dealing with aggressive and uncooperative people	N/A
Dealing with unpredictable behaviour	N/A
Job demands – high workload, tight deadlines, and competing priorities	Frequent
Exposure to traumatic or distressing content or situations – including handling sensitive information arising from patient records, patient care activities, incident reports, adverse events, or investigations of adverse events.	Rare
Role specific considerations Support is available for staff exposed to psychological risks. Any adjustments that may be required can be discussed with your manager.	
Definitions used to quantify frequency of tasks/demands as above	
Prolonged/constant	70 – 100 % of time in the position
Frequent	31 – 69 % of time in the position
Occasional	16 – 30% of time in the position
Rare	1 – 15% of time in the position
Not applicable	0% of time in the position

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Employee awareness and responsibilities

- Employees are required to be aware of, and work in accordance with, hospital policies and procedures.
- Employees are required to identify and report incidents, potential for error and near misses, to improve knowledge systems and processes and create a safe environment for staff and patients.
- Employees agree to provide evidence of a valid employment Working with Children Check and provide complete details for the Women's to undertake a Nationally Coordinated Criminal History Check (NCCHC).
- Our vision is a future free from violence and discrimination in which healthy, respectful relationships are the norm. The Women's expects all staff to contribute to a culture that promotes and supports diversity, equity, respect and inclusion.
- The Women's provides pregnancy termination services as part of its public health responsibility to provide safe health care to women.
- We are committed to the safety, wellbeing and empowerment of all children and young people. We prioritise an environment where children are protected and heard. We commit to safeguarding the social and emotional wellbeing of First Nations children, understanding that their connection to country, culture, kin and community is critical to their safety.

Vaccination requirements

As this role does not have direct patient contact, employees are strongly encouraged (although not required) to be vaccinated against COVID-19, influenza, whooping cough (pertussis), chicken pox and MMR (measles, mumps, rubella).

Declaration

By accepting this position description electronically I confirm I have read, understood and agreed to abide by the responsibilities and accountabilities outlined.

Developed date: September 2026

Developed by: Research Manager

Date of next review: September 2027

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