



Position Description

Title	Research Governance and Compliance Lead
Department	Research Office
Classification	A06
Agreement	Health & Allied Services, Managers and Administrative Workers (Victorian Public Sector) (Single Interest Employers) Enterprise Agreement 2021-2025
Responsible to	Research Manager

The Royal Women's Hospital

The Royal Women's Hospital (the Women's) has provided health services to women and newborn babies in Victoria since 1856 and is now Australia's largest specialist women's hospital. The Women's is recognised as a leader in its field, with expertise in maternity services and the care of newborn babies, gynaecology, assisted reproduction, women's health and cancer services.

The Women's Vision and Values

The Women's believes that health equity for all women is more than a vision; it is the essence of who we are and what we do encompassing our values, role and purpose.

The Women's Vision is: *Creating healthier futures for women and babies.*

Our values are: *Courage, Passion, Discovery and Respect.*

The Women's Declaration

The Women's Declaration reflects the principles and philosophies so fundamental to the hospital that they are the foundation on which rests everything we do. This is a declaration of the Women's role, function, purpose and promise:

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

Strategic Directions

The Women's Strategic Plan 2022 - 2025 contains four strategic priorities and fourteen initiatives of strategic focus, to achieve our vision of *Creating healthier futures for women and babies.*

The Women's four strategic priorities are:

1. We provide leading care for women and newborns
2. We partner to create exceptional experiences every day
3. We are the best place to work, learn and contribute
4. We lead and partner to influence change

Find the exceptional in your everyday.

The Women's, where you belong.

Department/Unit Specific Overview

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.

Responsibilities & Major Activities

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

Find the exceptional in your everyday.

The Women's, where you belong.

- 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

Development and review of relevant internal policies, procedures, guidelines and SOPs

Undertake any additional tasks as requested that reasonably fall within the scope of the position and classification

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.

Find the *exceptional* in your everyday.

The Women's, where you belong.

Key Selection Criteria

Experience/Qualifications/Competencies

- 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

Essential Criteria

- 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
- 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
- Competent computer literacy including use of a PC, mouse, keyboard, standard Microsoft office software
- Competence in document preparation using MS Word, MS Excel and MS PowerPoint

Desirable Criteria

- Post Graduate qualification in a science or health related field
- Experience in developing and implementing research governance, and/safety and quality initiatives
- 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.
- Exercises a high level of judgement.
- Demonstrates a capacity to consult and listen.

Find the *exceptional* in your everyday.

The Women's, where you belong.

- Balancing sometimes competing and conflicting priorities.
- Is open and approachable, and responds to the needs of various hospital departments and clinics in a timely and accessible way.
- Embodies a “can do” attitude and has a flexible approach to work.
- Has a professional demeanour.
- 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

Number of staff: 0
 Reporting Directly: 0
 Reporting indirectly: 0
 Total EFT: 0.6
 Budget Responsibility: 0

Find the exceptional in your everyday.

The Women's, where you belong.

Inherent Requirements

There are a number of critical work demands (inherent requirements) that are generic across all positions at the Women's. The generic inherent requirements for this position are detailed below. These may be added to with more specific inherent requirements, if required, by your manager and Occupational Health and Safety.

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
Attention to Detail	Prolonged/Constant
Working with distressed people and families	N/A
Dealing with aggressive and uncooperative people	N/A
Dealing with unpredictable behaviour	N/A
Exposure to distressing situations	N/A

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	0–15% of time in the position
Not Applicable	

Find the exceptional in your everyday.

The Women's, where you belong.

Employee Responsibilities and Accountabilities

- Be aware of and work in accordance with Hospital policies and procedures, including:
 - Code of Conduct
 - Confidentiality
 - Data Accountability Framework
 - Infection Control
 - Occupational Health and Safety
 - Patient Safety
 - Performance Development Management
 - Respectful Workplace Behaviours
 - Risk Management
- Be respectful of the needs of patients, visitors and other staff and maintain a professional approach in all interactions, creating exceptional experiences
- Undertake other duties as directed that meet relevant standards and recognised practice.
- Our vision is a future free from violence in which healthy, respectful relationships are the norm. The Women's expect all staff to contribute to a culture that promotes gender equity, respect and a safe working environment.
- The Women's provides pregnancy termination services as part of its public health responsibility to provide safe health care to Victorian women.
- Data integrity is an essential element of clinical and corporate governance and a key performance indicator for the Women's. The management of data influences and directly affects patient care, patient decisions, and ultimately the quality and reputation of our service delivery.

As a consequence all staff are responsible and accountable to ensure that (within their area of work):

- Data recording and reporting, (including RWH external reporting) is timely, accurate (i.e. error free) and fit for purpose
- Data management system policies and control processes are complied with on all occasions
- Where data issues and/or problems become apparent these matters are immediately referred and reported to supervisors/managers.
- Agree to provide evidence of a valid employment Working with Children Check and provide the necessary details for the Royal Women's Hospital to undertake a national Police check
- The Women's expects staff to identify and report incidents, potential for error and near misses and supports staff to learn how to improve the knowledge systems and processes to create a safe and supportive environment for staff and patients.
- Contributes to a positive and supportive learning culture and environment for health professional students and learners at all levels

Find the exceptional in your everyday.

The Women's, where you belong.

Staff Vaccination Requirements

COVID 19 Vaccination

Provide evidence that they have received a full COVID-19 Vaccination or provide evidence from a medical practitioner certifying that an exception applies related to a contraindication to the administration of the COVID-19 vaccination. This includes employees in all roles at the Women's Hospital. This requirement is in line with Directions issued by the Secretary pursuant to sections 42(1)(ca) and (h) of the *Health Services Act 1988* (Vic).

Influenza Vaccination

In line with the Health Services Amendment (Mandatory Vaccination of Healthcare Workers) Act 2020, some health care workers are now required to have their flu vaccination to work in health care. Evidence of vaccination is required.

[Manager to delete the option that does not apply]

As this role fits into category A or B of the departments risk ratings, applicants will be required to have been vaccinated against influenza. Evidence of vaccination is required.

As this role fits into category C of the departments risk ratings, applicants are strongly encouraged (although not required) to be vaccinated against influenza.

Statutory Responsibilities

- OHS Act 2004
- Freedom of Information Act 1982
- The Victorian Public Sector Code of Conduct

Declaration

I have read, understood and agree to abide by responsibilities and accountabilities outlined in this position description.

Developed Date: August 2023

Developed by: Manager Research

Date of next Review: August 2024

Find the exceptional in your everyday.

The Women's, where you belong.