



Human Research Governance Manager

Position title: Human Research Governance Manager

Division/Department: Governance, Risk and Compliance

Position reference:

Remuneration range:

Position reports to Head, Governance Risk and Compliance

Positions reporting to this one: Human Ethics Officer and Committee Convener (0.4)

Classification: HEW X

Work location: Parkville

Employment type: Full Time

Further information:

Closing date:

Position overview

The Human Research Governance Manager facilitates human research at WEHI by supporting the effective management of risk, compliance with industry standards, such as those of the NHMRC, and regulatory schemes.

The incumbent will have extensive experience in clinical research and clinical research governance. You will play a pivotal role in supporting researchers by assisting them with navigating the necessary processes to undertake human research at WEHI with focus on clinical trials. This includes creating greater certainty and transparency through the establishment of clear policies, procedures and guidelines.

The success of this role will be dependent on your ability to work collaboratively with different researchers and departments at WEHI, including the Clinical Translation Centre, Population Health, Business Development Office, Grants and Fundraising.

You will be responsible for developing and delivering training to support human ethics and working with the broader ethics team to develop a research governance manual.

Organisational environment

The Walter and Eliza Hall Institute of Medical Research

WEHI is one of Australia's leading biomedical research organisations, with a strong national and international reputation for performing highly influential basic and translational research.

With more than 1,100 staff and students, WEHI is addressing some of the significant health challenges of our time, with a focus on cancer, infection, inflammation, immune disorders, development and ageing. We are at the forefront of research innovation, with a strong commitment to excellence and investment in research computing advanced technologies and developing new medicines and diagnostics. And our researchers are strongly supported by Professional Services teams.

WEHI is organised around five themes; Cancer Research and Treatments; Infection, Inflammation and Immunity; Healthy Development and Ageing; New Medicines and Advanced Technologies and Computational Biology.

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This Institute is committed to delivering long term improvements in treating and diagnosing diseases, with many national and international clinical trials underway based on research undertaken at WEHI.

WEHI's main laboratories are located in the world-renowned Parkville precinct, a vibrant and collaborative life science research, education and healthcare hub. The Walter and Eliza Hall Institute Biotechnology Centre is located 30 minutes from Parkville at La Trobe University's R&D Park in Bundoora. It includes facilities for medicinal chemistry and antibody development and production.

Organisational objectives

Discovery and translation

To make discoveries that shape contemporary scientific thinking, increase understanding and improve prevention, diagnosis and treatment of cancer, immune disorders and infectious diseases.

Education and training

To educate and train world-class scientists and to attract, develop and retain the best and brightest workforce.

Organisational culture

To provide a vibrant and inspiring organisational culture that encourages, promotes and rewards excellence, collaboration, innovation, creativity and respect.

Engagement

To engage with our stakeholders to improve outcomes, building support and secure resources for medical research.

Sustainability

To build infrastructure, professional services and funding that sustains our research and maximises the time our scientists can spend making discoveries.

Organisational values

- Contribution to Society
- Integrity and Respect
- Collaboration and Teamwork
- Accountability
- Creativity
- Pursuit of excellence

Key responsibilities

Research Governance Framework and Quality Assurance

- Drive a program of continual improvement concerning human research governance at WEHI
- Provide support and advice on research governance, and regulatory requirements and channel queries to experts as required.
- Respond to new governance inquiries and compliance requirements proactively and engage relevant stakeholders to determine the risk implications to WEHI.
- In collaboration with key stakeholders:
 - Working with the broader ethics team establish and oversee a harmonised Research Governance Framework across key strategic areas that encompasses compliance requirements with all applicable laws and regulations for all research activities undertaken by WEHI.
 - Develop and effectively implement a Quality Management System for human research (policies and procedures) that underpin the Research Governance Framework, including clinical research conducted in Australia and overseas. Consider approaches in the broader ethics team and work collaboratively where appropriate.
 - Manage the program for monitoring and auditing human research compliance at WEHI.

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- Review human ethics applications concerning authorisation of projects using a risk management approach to facilitate the approval of high quality and ethical research.
- Establish information resources and training to aid in educating staff and students on governance requirements and responsibilities.
- Support the development of educational sessions and workshops.
- Administer the Research Governance Framework concerning human research to support compliance with relevant legislation and codes of practice.
- Maintain a working knowledge of current legislation and other guidelines related to research governance and quality assurance requirements.
- Working with relevant teams coordinate the development and effectiveness of human research and clinical trial risk register.
- Work closely with the Governance, Risk and Compliance team, researchers, business development office and other key areas to manage the implementation of a harmonised Research Governance Framework.

Staff Management

- Actively contribute to a harmonious team, both from a cultural and work output perspective.
- Proactively contribute to the continuous improvement of services and active participation in process review activities.
- Provide managerial support and mentorship to direct reports, including performing staff continuing professional development programs.
- Share relevant and applicable knowledge, training and mentoring of new staff as appropriate.
- Champion Institute policies and role model compliance.
- Foster an atmosphere of good staff morale and achieve a high level of staff retention.

Regulatory

- Develop effective systems to ensure compliance with all relevant regulatory instruments.

Administrative

- Review policies, procedures and SOPs within the agreed timelines.

Communication

- Establish and maintain strong working relationships with relevant researchers, WEHI's Clinical Translation Centre and all professional service teams to ensure clear and open communication at WEHI.
- Serve on and advise WEHI committees as appropriate.
- Maintain a professional relationship with external clients, use discretion and diplomacy in all dealings.
- Actively promote and strong ethical research culture and foster a work environment that encourages close co-operation between ethics, governance and compliance staff and researchers.

Key selection criteria

Personal qualities

- Excellent oral and written communication skills with the ability to relate to colleagues at all levels.
- Excellent time management and practical problem-solving skills, with the ability to identify and rectify issues.
- Confidentiality, discretion, sound judgment and attention to detail.
- Ability to provide team leadership while acknowledging everyone's contribution to the shared endeavor.
- Demonstrated ability to liaise with other service departments in an effective and collegiate manner.
- Demonstrated honesty and integrity and ability to work within the shared values of WEHI, including

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respect for others, a commitment to working collaboratively, creative, accountable.

- Recognition of the needs of the scientific community at WEHI and the ability to understand researchers' needs from their perspective.

Knowledge and skills

- Appropriate tertiary qualification in a relevant field such as science, health or ethics.
- Extensive experience in clinical research governance and/or clinical research, preferably within a hospital, medical research institute or contract research organisation environment. Including knowledge of conducting trials overseas/global health.
- In-depth knowledge of the legislation and relevant codes relating to clinical trials including the NHMRC Australian Code for the Responsible Conduct of Research; NHMRC National Statement of Ethical Conduct in Human Research; Guideline for Good Clinical Practice; National Clinical Trials Governance Framework and the application of *Therapeutics Goods Act 1989*.
- Experience in developing processes and procedures within a policy framework,
- In-depth understanding of the health and medical research environment in Victoria and Australia. Broad understanding of the medical research and clinical trial environment overseas.
- Proven ability to manage a staff of varying experience and abilities.

A safe and sustainable workplace

WEHI is committed to developing a safe and sustainable workplace with rigorous risk, compliance and governance systems. As an employee, you are expected to:

- Comply with Institute policies, plans and procedures.
- Take reasonable care of your own safety and the safety of others, including using Personal Protective Equipment (PPE) and safety devices appropriately.
- Report all risks, hazards, incidents/injuries and near misses.
- Attend, and complete training programs as documented in individual training needs matrices, within the proposed time frame.
- To the extent of your role responsibilities and obligations, proactively contribute to a safe and **sustainable workplace**.

Diversity

At WEHI, we embrace diversity amongst our staff and students and know the importance of a inclusive workplace culture to the success of our organisation.

We are actively committed to achieving gender equality across our workforce. WEHI has a range of policies and initiatives in place to address the under-representation of women at senior levels and to support people with caring responsibilities.

We have a strong commitment to the process of reconciliation and creating meaningful employment and training opportunities for Aboriginal and Torres Strait Islander Peoples.

We encourage applications from people from culturally and linguistically diverse backgrounds, Aboriginal and Torres Strait Islander Peoples, people with a disability, and people from the LGBTQIA+ community.

Privacy notification

The collection and handling of declarations and personal information relevant to your employment will be consistent with the requirements of the Privacy Act 1988.

Acceptance

I,have read, understood and agree that this position description represents the key duties and responsibilities expected of me while employed in this position. I will also undertake other duties assigned to me from time to time. I understand the Walter and Eliza Hall Institute of Medical Research reserves the right to modify this position description, as required, and I will be consulted when this occurs.

**) If e-signature is used:*

I consent to providing my electronic signature below in confirmation that I have read, understood and accept the duties and responsibilities described this position description.

Employee Signature: Date:

Supervisor Signature: Date:

Supervisor Name: Date: